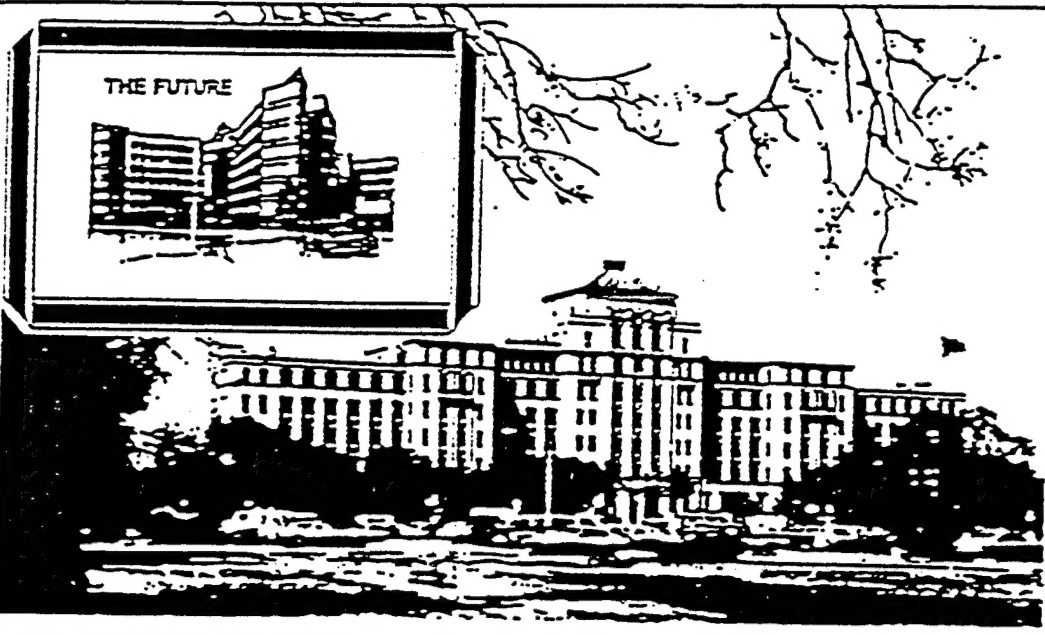


DEPARTMENT OF CLINICAL INVESTIGATION

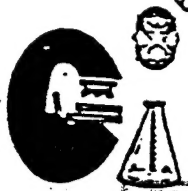
# ANNUAL RESEARCH PROGRESS REPORT

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VOLUME II



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Detail Summary Sheet

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Date: 1 Dec 95      Protocol Number: A-93-03      Status: Ongoing

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Title: Hypothyroid Induced Hypometabolic State as a Possible Diagnostic and Therapeutic Maneuver as Tested in a Mouse Model Utilizing PET Scanning

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Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center
Department/Service: Medicine/Endocrinology	Associate Investigator(s): COL Albert Thomason, MC LTC Ian Thompson, MC Isidoro Chapa
Key Words: Mouse, Mus musculus, PET	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

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Objective(s): Mice will be injected in the thigh with a mouse bladder cancer cell line and then randomized to an induced hypothyroid arm and a control arm. A PET scan will then be done to assess the metabolic status of the tumor burden verses the rest of the mouse body.

Technical Approach: Mouse bladder cancer cells maintained in cell cultures will be injected into the thigh of the mice. The mice will then be randomized to one of two groups: euthyroid and hypothyroid with the later induced by medication. PET scans using radioactive isotopes tagged glucose will then be done to see if the tumor masses are affected by thyroid hormone manipulation as compared to the rest of the mouse body.

Progress: Project is currently on hold due to funding issues with PET Scan at UTHSC. We pay nothing to use so we only go on standby.

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# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: A-93-04                      Status: Ongoing

Title: Production of Monoclonal Antibodies to Rhodanese and Chaperonin Epitopes in Ascites Tumors in BALB/c Mice for Use as Molecular Probes in Support of Clinical Investigation Protocol C-18-88

Start date: 30 Jul 93	Estimated completion date: Oct 94
Principal Investigator: Gerald Merrill, Ph.D.	Facility: Brooke Army Medical Center
Department/Service: Clinical Investigation	Associate Investigator(s): Kimberly Doody
Key Words: Mouse, Mus musculus, Monoclonal Antibodies, Ascites Tumors, Tumors, Rhodanese, Chaperonins	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date:                      Review results:	

Objective(s): To produce monoclonal antibodies to specific epitopes on rhodanese and the chaperonins (CPN<sub>60</sub> and CPN<sub>10</sub>) for use as biochemical molecular probes.

Technical Approach: As outlined in the research protocol.

Progress: Ten mice have received two immunizations with chaperonin-adjuvant immunogens. Four mice have been immunized against CPN<sub>60</sub>, three immunized against CPN<sub>10</sub> and the remaining three immunized with DNA K. All 3 proteins have been prepared in lipid micelles containing trehalose dimycolate and monophosphoryl lipid A (RIBI adjuvant system). A volunteer technician has been trained to perform ELISA screening/titering of sera. The four mice immunized with CPN<sub>60</sub> were screened for antibodies to CPN<sub>60</sub>. All four mice demonstrated anti-CPN<sub>60</sub> antibodies when screened at a 1:10 dilution as compared to normal mouse sera (obtained commercially) at the same dilution. Two of these CPN<sub>60</sub> positive mice were, on separate occasions, given a third immunization (IV) and euthanized three days later. Their spleens were removed for fusion to SP2/0 culture lymphocytes. Following fusion, numerous HAT resistant colonies were observed indicating a successful procedure for forming hybridoma cells. However, neither fusion resulted in a colony of cells that produced ant-CPN<sub>60</sub> antibodies (as evidenced by ELISA). Due to the excessive

A-93-04 (continued)

age of the mice that had received immunizations, it is unlikely that the cells of their spleens would result in successful fusions. The remaining 6 mice were therefore sacrificed by the technicians of the DCI animal facility. The military technician who had been trained in tissue culture techniques for propagation and closing of the hybridomas generated by this fusion has departed DCI. A BRAG volunteer has been trained in these techniques and is presently prepared to attempt a fusion. Myeloma SP2/0 cells have been propagated successfully by this volunteer without contamination and have viability exceeding 90%. Three mice have been ordered to immunize with CPN<sub>60</sub>. However, prior to immunization a small blood sample (500 ul) will be obtained from each mouse for use as a negative pre-immune control (instead of commercial normal mouse serum) in ELISAs to screen the effectiveness of immunization prior to sacrifice of an animal for its spleen.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-93-05 Status: Terminated

Title: Evaluation of a Prototype Double Lumen Multiorificed Catheter for Resuscitating Swine from a Lethal Air Embolism

Start date:	Estimated completion date:
Principal Investigator: MAJ Jon Hinman, MC	Facility: Brooke Army Medical Center
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): MAJ Paul Mongan, MC
Key Words: Swine, Porcine, Sus scrofa, complications: air embolism, position: sitting, surgery: neurosurgery	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the flow characteristics of the Cook Critical Care double lumen multiorificed catheter. 2) To establish the lethal dose of air (ml/kg) embolized into the sagittal sinus of a swine. 3) To evaluate the percentage of an air embolus aspirated by a Cook Critical Care double lumen multiorificed catheter. 4) To evaluate the ability of the Cook Critical Care double lumen multiorificed catheter to resuscitate a swine model from a lethal venous embolus. 5) To compare the results of a Cook Critical Care double lumen multiorificed catheter against an accepted standard; the Bunegin-Albin 16 Ga multiorificed catheter (flow, % aspiration, resuscitation).

Technical Approach: As outlined in the research protocol.

Progress: Study has been terminated. Results have been finalized and manuscript was prepared.

# Detail Summary Sheet

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Date: 1 Dec 95      Protocol Number: A-93-06      Status: Ongoing

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Title: Titanium 13-13 Internal Fixation Plates in Comparison to CP Titanium Plates in the Healing of Long Bone Osteotomies in a Goat Model

Start date:	Estimated completion date:
Principal Investigator: CPT Christopher Vaughn, MC	Facility: Brooke Army Medical Center
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): COL Allan Bucknell, MC CPT Matthew Horton, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if Titanium 13-13 Plates perform more effectively in long bone fracture fixation than CP Titanium plates, decreasing the time to union, increasing ultimate strength and reducing stress shielding.

Technical Approach: A total of twenty (20) adult domestic goats will be studied. Plates will be placed on the lateral side of each femur. Plates used will be six to eight hole, narrow elongation plates. Six to eight goats will be sacrificed, and histologic and microbiologic setting will be performed.

Progress: We have completed the implant, euthanasia and specimen harvesting; Have yet to complete data collection on specimens. Study is completed but will remain open until April 1996.

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# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-01 Status: Ongoing

Title: Effect of Topically Applied Crystalline L-lysine on Wound Healing in the Guinea Pig

Start date: 25 Oct 93	Estimated completion date:
Principal Investigator: Eleanor Ayala, MA	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): MAJ Earl Grant, Jr., MS
Key Words: Guinea Pig, Cavia porcellus, wound healing, skin punch biopsies, topical therapy, L-lysine, elastin	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the topical application of crystalline L-lysine enhances reepithelialization and minimizes scar formation in healing punch biopsies using the hairless guinea pig model.

Technical Approach: Four male, 500-600g, euthymic hairless Hartley guinea pigs will be used. Test agent will be applied to each of four test sites on one side of the animal (determined by card shuffle) and no agent will be applied to the four contralateral control sites.

Progress: Wound contraction was significantly retarded in the lysine treated sits. Histological stains showed that the treated sites had filled in with collagen. The monoclonal antibodies to fibroblasts and macrophages were not effective on formalin-fixed, paraffin-embedded tissues. An addendum is being submitted to identify elastin, collagen type and substance P in the formalin-fixed, paraffin-embedded tissues.

# Detail Summary Sheet

Date: 1 Oct 95      Protocol Number: A-94-02      Status: Ongoing

Title: Bleeding Complications Due to Pulmonary Hypertension in Sheep (Ovis aries) Undergoing Transbronchial Biopsy

Start date: 15 Nov 93	Estimated completion date:
Principal Investigator: MAJ Michael J. Morris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): MAJ Mark Peacock, MC LTC William C. Lloyd, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This project will determine if there is an increased risk of significant hemorrhage from transbronchial biopsy secondary to pulmonary hypertension. A sheep model with experimentally-induced pulmonary hypertension will be utilized as the basis for this protocol.

Technical Approach: Ten adult sheep, weighing 25-35 kg will be used. Sheep will be anesthetized with ketamine, xylazine and atropine. Once anesthetized, the right subclavian vein will be instrumented with a polyvinyl catheter and a pulmonary artery catheter will be inserted into a pulmonary artery. The carotid artery will be cannulated to continuously monitor systemic arterial pressures.

Progress: Study is complete and data has been compiled. Results were published in a manuscript which was accepted for publication.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-03 Status: Ongoing

Title: An Improved Histological Method for Hydration and Preservation of Tissue Morphology in Normal Guinea Pig (Cavia porcellus) Pancreas

Start date: 16 Dec 93	Estimated completion date:
Principal Investigator: Eleanor Ayala, MA	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): LTC Michael H. Enghardt, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the substitution of a glycerol solution for the alcohols routinely used during the rehydration of formalin-fixed, paraffin-embedded tissue will give better preservation of morphology of normal guinea pig pancreas.

Technical Approach: Tissue from four male, 500-600g, euthymic hairless Hartley guinea pigs will be used. After euthanasia under a previous IACUC protocol, the pancreas from each euthanized animal will be collected and placed in zinc-formalin fixative for 24 hours at room temperature. A 5mm cube of tissue will be cut through the center of each pancreas and embedded in paraffin. Sixteen serial sections will be cut from each paraffin block. Sections will be kept in numerical order so that alternating slides will form two groups of eight slides each. One set will serve as control and will be processed by the routine fixation procedure using alcohol. The other set will serve as test and will be processed by the modified fixation technique using glycerol instead of alcohol.

Progress: No differences were observed between tissue processed by the routine histological procedures and the modified procedure employing glycerol solutions. There was no unfavorable alteration of tissue. The procedures approved in addendum #1 are currently being tested manually and will be tested

A-94-03 (continued)

on the routine automatic processor. The successful outcome of this procedure will complete the tissue processing from formalin fixation to embedding, sectioning and staining and application of a patent for the process.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-04 Status: Ongoing

Title: Reversible Transient Hypothyroid Induced Hypometabolic State as a Possible Therapeutic Maneuver for Breast Cancer (Using Mus musculus)

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): CPT Alisan Kula, MC COL Albert Thomason, MC
Key Words:	Isidoro Chapa Gerry Merrill
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To show at the rudimentary cellular level the growth of breast cancer cells is independent of the variable levels of thyroid hormone they are cultured in. We expect there to be little effect upon growth in culture despite variable levels of thyroid hormone in the serum free culture medium.

Technical Approach: If the above indicates on a cellular level that breast cancer cells are relatively independent of thyroid hormone, then we will examine breast cancer cells in vivo. This will be done by the injection of breast cancer cells into mice thighs and randomization into control arm and hypothyroid arm. Radioactive tagged C14 glucose will then be injected into the mice as an indirect measurement of metabolism.

Progress: MgSO<sub>4</sub> and digoxin were shown to have an additive effect in prolonging A-V conduction.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-05 Status: Ongoing

Title: The Effect of Magnesium on Ventricular Rate Control During Atrial Fibrillation

Start date: 1 Dec 93

Estimated completion date:

Principal Investigator:  
Bernard J. Rubal, Ph.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Cardiology

Associate Investigator(s):  
MAJ Maureen A. Arendt, MC  
John Ward, Ph.D.

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To examine the efficacy of parenteral  $MgSO_4$  in the acute management of rapid ventricular rates in an animal model with atrial fibrillation, and 2) to determine whether  $MgSO_4$  and digoxin have additive effects in controlling ventricular rates.

Technical Approach: All animals will be given 0.07 mg/Kg digoxin intravenously after the initial 30 minute period and followed for 3.5 hours. Ventricular rates will be obtained at baseline, every five minutes for the first 30 minutes, and then every 30 minutes for 3.5 hours. In addition to ventricular rate control, the hemodynamic stability of  $MgSO_4$  therapy will be assessed.

Progress: Study is still ongoing. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-06 Status: Ongoing

Title: An Experimental Rat Model of Post-Pneumonic Empyema

Start date: 1 Apr 94	Estimated completion date:
Principal Investigator: MAJ Michael J. Morris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary	Associate Investigator(s): LTC J. Wm Kelly, MC MAJ Julia Morgan, MC CPT Robert Durnford, MC CPT Thomas Mego, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Development of dose response curve by administration of different aerobic bacteria in various concentrations by direct tracheal inoculation into rat lungs to determine which organism will cause pneumonia and empyema without causing sepsis. 2) Development of a rat model of post-pneumonic empyema which can be reliably reproduced in at least 70% of animals infected with less than 10% mortality.

Technical Approach: Rats will be anesthetized with 60mg/kg Ketamine and 4mg/kg Rompun IM prior to the procedure. Inoculation will be accomplished using a modified 16 gauge intravenous catheter of at least two inches in length. The needle stylet is to be modified by cutting the end of the needle and filing it down smooth. The needle will be bent to a 145 degree angle to conform with the rat's oral airway. The modified needle will be inserted into the trachea and proper placement will be confirmed by palpation of the needle against the cartilaginous rings of the trachea. An 18 gauge pediatric central venous catheter will be passed through the needle and down the left mainstem bronchus. Alternately, a semirigid 3.5 plastic catheter will be used after visualization of the vocal cords with an otoscope.

Progress: Study is still ongoing. There is currently no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-07 Status: Ongoing

Title: Production of Mouse Positive and Negative Control Slides for Use in Rabies FA Test

Start date:	Estimated completion date:
Principal Investigator: David Culak	Facility: Brooke Army Medical Center, Texas
Department/Service: Regional Veterinary Laboratory	Associate Investigator(s): Michael Gray
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To produce negative and positive control slides for use in the Rabies Fluorescent Antibody Test (FA). One negative and one positive control slide are used for each FA test performed on diagnostic specimens.

Technical Approach: Twelve, 3-5 week old mice are anesthetized with halothane and then injected intracranially (IC) with 0.03 mg of CVS-11 rabies virus suspension utilizing a 1/4 inch, 27 gauge needle and tuberculin syringe. Mice injections will be performed in Bldg 2630, room 169. Inoculated mice will be observed daily for signs of rabies infection. As mice exhibit symptoms of rabies and become moribund, they are humanely euthanized by CO<sub>2</sub> asphyxiation (exposure to 100% CO<sub>2</sub> for five minutes). After mice are dead, brain and brain stem are collected, impression smears prepared and slides held at -70 degrees C for future use.

Progress: We have not had to prepare control slides this year. We will have enough for another year. A new set of control slides will be made at a later date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-08 Status: Ongoing

Title: Blood Amplification: Use of Phosphoenolpyruvate (PEP) Treated Red Blood Cell Transfusions in the Dog (Canis familiaris)

Start date:	Estimated completion date:
Principal Investigator: LTC Rhonda L.S. Cornum, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): MAJ Russell Martin, MC CPT Christopher Bandy, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if transfusion with PEP treated RBCs maintains oxygen consumption with less increase in cardiac output than control transfusion in anemic hypoxia, in the anesthetized dog.

Technical Approach: Adult, splenectomized dogs weighing 8-15 kgs will be used. On the day of surgery, they will be fasted overnight, and anesthesia induced and maintained with 2-3% isoflurane. Ventilators will be set to deliver 10 breaths per minute (10 cc/kg body weight) at 60% oxygen and adjusted to maintain a PCO<sub>2</sub> between 35-45. A 5 French Swan-Ganz catheter will be placed via the external jugular vein to allow mixed venous blood sampling and determination of cardiac output by thermodilution.

Progress: There have been no substantial changes in part I of A-94-08. The protocol is active and there is only one substantive change, the estimated time of completion. Delays in funding transfer from MRDC to BAMC and receiving equipment makes the revised estimated completion date of December 1995. Fourteen dogs have been splenectomized to date. One died postoperatively and three have been used in the experimental protocol. The model of euvolemic anemia causing a marked increase in cardiac output in the dog has been established. All the required equipment has been procured, and the blood treatment methodology verified. No trends can be predicted yet.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: A-94-09      Status: Ongoing

Title: Botulinum Toxin Detection by Mouse Bioassay

Start date:	Estimated completion date:
Principal Investigator: Michael Gray	Facility: Brooke Army Medical Center, Texas
Department/Service: Regional Veterinary Laboratory	Associate Investigator(s): David Culak
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish and maintain a standing procedure for the mouse bioassay as a means for detecting Clostridium botulinum neurotoxin in cultures, food extracts, serum, and fecal specimens.

Technical Approach: Specimens such as food, can products, patient serum and feces suspected of containing botulinum toxin will be submitted to this laboratory for analysis. In order to rule out suspect botulinum toxin in a patient, the mouse bioassay is used which is rapid, specific, and sensitive. Specimens are processed, divided into three groups: non-heated, heated, and non-heated with antitoxin. Mice are sedated, inoculated IP with 0-5 ml of specimen and appropriated botulinum toxin controls (non-heated, heated, and nonheated with antitoxin) and observed for typical signs of the neurotoxin.

Progress: The number of mice used to test three specimens exceeded the 72 mice authorized by this protocol. However, we were unable to predict the demand of mice because it was dependent upon the number of samples we received.

94-1702	13 Jul 94	McLeod - Stool Sample	25 mice
94-2343	12 Oct 94	Lipinski - Stool/Serum	25 mice
94-0244	17 Feb 95	Multiquist-Stool	25 mice



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-10 Status: Ongoing

Title: Biosynthesis of Polyclonal Anti-peptide and Anti-protein Antibodies in Rabbits (Replaced A-90-09)

Start date:	Estimated completion date:
Principal Investigator: Gerald R. Merrill, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To produce polyclonal antisera to peptides and proteins for use in conformational studies of selected proteins and for development and use in immunoassays for quantification of proteins.

Technical Approach: Rabbits will be acclimated for 7 days prior to obtaining an initial blood sample. No more than 6 rabbits will be used at any period. Blood will be drawn into heparinized syringes via ear arteries by animal facility personnel. Prior to venipuncture, the rabbits will be placed into restraint and the hair removed on one ear using hair clippers. Alcohol will be sprayed onto the ear prior to venipuncture to improve the visibility of the vein and to disinfect the venipuncture site.

Progress: There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: A-94-11 Status: Ongoing

Title: Temperature Monitoring During Craniotomy: A Comparison of Core Temperature Monitoring with Regional Cortical Brain Temperature During Active and Passive Heat Exchange in the Porcine Model (Sus scrofa) of Intracranial Surgery

Start date:	Estimated completion date:
Principal Investigator: MAJ Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this investigation is to describe the correlation between brain temperature and core temperature during a porcine surgery model.

Technical Approach: Temperatures will be measured from exposed and unexposed areas of the brain and central blood vessels of the body. The temperatures of the animals will be allowed to decrease as is common during surgery. After the cooling period, the animals will be warmed to a normal temperature as is done in surgery. The changes in temperature in the brain and the central veins will be evaluation. This information will better define the limits of cooling and rewarming during brain surgery. This knowledge will help patients undergo surgery more safely.

Progress: Study remains ongoing. Data collection continues.

### Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: A-95-01 Status: Ongoing

Title: Optimal Pleurodesis: A Comparison Study of the Effects of Pleural Abrasion

Start date: 28 Dec 94	Estimated completion date:
Principal Investigator: MAJ Michael Halligan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery Service	Associate Investigator(s): CPT James Obney, MC COL Greg A. Bowman, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the abilities of tetracycline, doxycycline, TALC and HCL to effect pleurodesis relative to the gold standard of pleural abrasion in the rabbit pleura.

Technical Approach: Sixty rabbits will be randomized into six treatment categories. Both hemithoraces will be utilized for a total of 12 hemothoraces. Twenty will receive thoracotomy and mechanical pleurabrasion under general anesthesia with post-op analgesia. The remainder will receive intrapleural instillation of a randomly assigned sclerosing agent with post-procedure and analgesia.

Progress: There is no data available at this time. Study is ongoing. An annual review is required during the month of December 1995.

# Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: A-95-02 Status: Ongoing

Title: Flow-Wire Validation Study in the Porcine Model (Sus scrofa)

Start date: 12 Jan 95	Estimated completion date:
Principal Investigator: MAJ Howard Zimring, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology Service	Associate Investigator(s): Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To validate the Flo-wire measurement of coronary flow velocity and coronary flow reserve in an in vivo highly controlled preparation during various hemodynamic conditions.

Technical Approach: Animals will be instrumented and allowed to reach steady state at a paced heart rate of 90 bpm and coronary perfusion pressure of 90 mmhg. Hematocrit and oxygen saturation will be assayed at least once every half-hour to insure stability of the pacemaker. Also, ventricular function will be continuously monitored by the use of segment shortening ultrasound crystals to avoid changes in coronary blood flow due to changes in ventricular function.

Progress: There is no data at present to report. An annual review will be conducted in January 1996.

# Detail Summary Sheet

Date: 15 Nov 95      Protocol Number: A-95-03      Status: Ongoing

Title: Effect of Hormone Containing Hair Preparations on Sexual Development in Guinea Pigs

Start date:	Estimated completion date:
Principal Investigator: COL Chandra Tiwary, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): CPT Nick Geraldo, M.D. MAJ Kevaghan P. Fair, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To observe the effect of topical applications of hormone-containing hair products on the a) sexual development, b) sexual organs, and c) estrogen, androgen levels of sexually immature guinea pigs.

Technical Approach: Estrogen-containing cream will be applied daily on the body of animals and signs of estrogenic activity will be noted. About 3-4 ml of serum (blood obtained via cardiac stick) will be obtained and kept for hormone analysis.

Progress: Study has been on hold pending receipt of hairless guinea pigs. Because of the difficulty in obtaining the guinea pigs, a request to change the animal species was presented by the investigator and approved expeditiously by the Institutional Animal Care and Use Committee. The investigator is currently awaiting the procurement of hairless rats in order to begin his study.

# Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: A-95-04 Status: Ongoing

Title: Extreme Hemodilution: Cerebral Electrophysiologic and Metabolic Function

Start date:	Estimated completion date:
Principal Investigator: MAJ Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): MAJ John L. Fontana, MC (WRAMC)
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To define the tolerable and intolerable limits of hemodilution in relation to the cerebrovascular, neurophysiologic and cerebral metabolic effects of extreme hemodilution.

Technical Approach: After fasting overnight, swine will be induced with halothane by nose cone titrated to effect. The animals will be endotracheally intubated and ventilated to maintain ETCO<sub>2</sub> at 35-40 mmhg. Anesthesia will be maintained with halothane. After vascular access is secured, 30 mg/kg of fentanyl, 0.2 mg/kg midazolam, and 0.2 mg/kg of vecuronium will be administered, the halothane will be discontinued and anesthesia will be maintained with fentanyl 0.2 mg/kg/hr and midazolam 0.2 mg/kg/hr.

Progress: Study is on hold awaiting word on application for research grant from US Army Medical Research Materiel Command.

# Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: A-95-05 Status: Ongoing

Title: The Effect of Iron Depletion with Deferoxamine on CCl<sub>4</sub> Induced Cirrhosis in Male Wistar Rats, Rattus norvegicus.

Start date: 6 Jul 95	Estimated completion date:
Principal Investigator: MAJ Michael A. Riel, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology Service	Associate Investigator(s): COL Shailesh Kadakia, MC LTC William W. Brinkley, VC (ISR)
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if iron depletion using deferoxamine will alter the degree of cirrhosis induced by CCl<sub>4</sub>.

Technical Approach: Groups I and II will have phenobarbital added to their drinking water for 2 weeks prior to carbon tetrachloride gastric instillation and will occur weekly for 8 to 10 weeks, until ascites develops manifested by bulging flanks. The placement of the carbon tetrachloride in the rats' stomach will be accomplished by placing a tube in the animals stomach through its mouth while it is under general anesthesia.

Progress: This is a new study. There is no reportable data.

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Detail Summary Sheet

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Date: 1 Dec 95 Protocol Number: T-92-01 Status: Terminated

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Title: Sensormedics Model 3100 High Frequency Oscillatory Ventilator Training using a Swine Model

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Howard Heiman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

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Objective(s): This training protocol is designed to teach physicians and other health care professionals the basic knowledge required to use and operate a Sensormedics Model 3100 High Frequency Oscillatory Ventilator.

Technical Approach: As outlined in the training protocol.

Progress: The training is now being done with human subjects.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-92-02 Status: Ongoing

Title: Pediatric Endotracheal Training Utilizing the Ferret Model

Start date: 20 May 92	Estimated completion date:
Principal Investigator: Stephen C. Inscore, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This protocol is designed to teach physicians and other health care providers the basic knowledge and psychomotor skills required for efficient endotracheal intubation in children.

Technical Approach: Protocol designed to increase physician confidence in intubation skills and increase the efficiency with which invasive airway management is accomplished in emergencies.

Progress: 125 students were trained in the PALS course at BAMC during the last twelve months. This training is required at BAMC by JCAHO recommendations. Cost to train these students at a civilian facility would be \$31,250.00 plus per diem.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-93-01 Status: Ongoing

Title: Resident Training in Microsurgical Technique

Start date: 7 Dec 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This training protocol is designed to instruct resident physicians in the basic techniques of microsurgery required for reproductive surgery.

Technical Approach: During their three-month rotation on the Reproductive Endocrinology Service, OB-GYN resident physicians will perform or assist with approximately 10-12 operations in which the operating microscope is used for repair or anastomosis of the fallopian tube.

Progress: 10-12 residents and medical students received instruction in microsurgical technique. This is a vital part of resident training and has direct impact upon their surgical technique in the OR.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: T-93-02                      Status: Ongoing

Title: Oral and Maxillofacial Surgery's Microneurosurgery Laboratory  
Utilizing Rats

Start date: Feb 93	Estimated completion date:
Principal Investigator: COL James M. Startzell, DC	Facility: Brooke Army Medical Center
Department/Service: USA DENTAC	Associate Investigator(s): COL John P. McLaughlin, DC LTC Andrew A. Vorono, DC MAJ Matt Conklin, MC
Key Words: Rattus norvegicus, micro-surgery, microneurosurgery, sciatic nerve, nerve repair, neurorrhaphy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To introduce oral and maxillofacial surgery residents to microneurosurgery and to prepare them for the applications of those skills to human patients. To provide a method for the advancement and maintenance of microneurosurgery skills in previously training oral and maxillofacial surgery staff members.

Technical Approach: Prior to utilizing rats, one to two practical sessions will be conducted at the animal lab site. These sessions will introduce the residents to the operating microscope and loops, to microsurgery instruments and sutures, cloth and plastic materials, rather than animals. Animal phase of training will be scheduled based on the individual's progress in this pre-animal clinic.

Progress: The microsurgical technique lab has not been active since February 1994. Due to illness of one of our teaching staff this left only two staff and with no weekend availability of the rat lab, it was impossible to continue the lab and still keep up with clinical business. The rat lab was placed on hold until such time that adequate teaching staff is obtained.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-93-04 Status: Ongoing

Title: DEPMEDS War Surgery Training

Start date: 2 Oct 93	Estimated completion date: 20Oct93
Principal Investigator: COL Greg Bowman, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To train personnel in: a) fundamental principles of abdominal and thoracic war surgery, and b) the use and limitations of the DEPMEDS environment and equipment.

Technical Approach: Animals will be transported by veterinary personnel to the DEPMEDS site in approved cages and vehicles. Induction and maintenance inhalant anesthesia and life support will be provided by anesthesia personnel with the assistance of veterinary personnel. Animals will be positioned in dorsal recumbency then sterilely prepped and draped for aseptic surgery by operating room nursing personnel. Surgeons will perform splenectomy, small bowel resection with enteroenterostomy, colon resection with end colostomy, thoracotomy, and pulmonary resection. Surgeons will perform open reduction/internal fixation of simulated diaphyseal fracture.

Progress: The principal investigator (PI) departed the Army. This study has been placed in a hold status until such time that a new PI has been assigned.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-94-01 Status: Ongoing

Title: Cardiology Fellow and Cardiovascular Technologist Hemodynamic Training Protocol

Start date: 25 Oct 93	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Cardiology/Medicine	Associate Investigator(s): MAJ William T. Wright, MC Raymond Tamez James R. Bulgrin
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Training protocol is designed to instruct first year Cardiology Fellows and cardiovascular technologists (cath technicians) in basic hemodynamic principles, concepts in bioinstrumentation, physiologic recording procedures, and endomyocardial biopsy techniques.

Technical Approach: Right and left heart pressures, coronary flow, and thermal dilatation cardiac outputs will be monitored during steady state, ventricular pacing, altered preload and afterload states, and during acute coronary occlusion.

Progress: Three physicians and eight cardiovascular technologist participated in this training protocol. The cardiovascular technologist performed a task done by physicians in the clinical environment. This experience proved to be rewarding allowing them to more fully understand cardiac catheterization procedures and cardiac physiology. Physicians (Cardiology Fellows) benefitted by the improvement of technical skills, particularly in regard to catheter and wire manipulation.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-94-02 Status: Ongoing

Title: Cardiothoracic Surgery Service Porcine Surgery Using Swine (Sus scrofa)

Start date:	Estimated completion date:
Principal Investigator: COL Greg A. Bowman, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/ Cardiothoracic Surgery	Associate Investigator(s): COL David Cohen, MC MAJ Mark Nyreen, MC MAJ Peter Napoli, MC MAJ John Carter, SP CPT Ann Johnson, SP
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Basic proficiency training of surgical housestaff in general cardiothoracic surgical techniques in extracorporeal perfusion techniques. 2) Advanced/refresher proficiency training of staff surgeons and perfusionists in new state-of-the-art or seldom used cardiothoracic surgical techniques or extracorporeal perfusion techniques.

Technical Approach: Training lab will be conducted on an ad hoc basis as determined by the instructor staff. Thoracic Surgery will provide personnel to set up and operate the heart-lung machine. LARF will be given not less than 4 weeks notice that a laboratory session is requested for a specific date and time. One pig shall be used for each laboratory session except in the case of heart transplants. Multiple procedures will be performed on the recipient animal prior to performing the transplant procedure.

Progress: Low dose heparin cardiopulmonary bypass techniques tested and refined.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-94-03 Status: Ongoing

Title: Basic General/Vascular Surgical Technique Training Laboratory Using a Porcine Model

Start date:	Estimated completion date:
Principal Investigator: COL Johnny Alvarez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/General Surgery	Associate Investigator(s): COL Robert Solenberger, MC Ralph Wheeler, M.D. David Olson, M.D. Russell Martin, M.D. William Bradshaw, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Basic proficiency training of surgical concerns, surgical residents, and other select surgical ancillary personnel approved by the principal instructor(s) in general soft tissue and vascular surgical techniques (both laparotomy and laparoscopic procedures. 2) Advanced/refresher proficiency training of staff surgeons in new state-of-the-art or seldom used soft tissue and vascular surgical techniques.

Technical Approach: Training laboratory shall be conducted twice monthly (normally the 2nd & 4th Thursday of each month). Each laboratory session shall be scheduled for 1300-1600 hours on the appointed day. One pig shall be used for each laboratory session. At least one instructor shall be present and conduct each training session.

Progress: There is no reportable data at this time.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: T-94-04 Status: Ongoing

Title: Pediatric Advanced Life Support Skills Laboratory Using the Goat (Capra hircus)

Start date: 1 May 94	Estimate Completion Date: 1 May 95
Principal Investigator: LTC Stephen Inscore, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): MAJ Mark Hays, MC MAJ Michael Battista, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To teach or refresh Pediatric Advanced Life Support (PALS) skills to Pediatric Department residents with basic procedural skills in pediatric resuscitation as required by the American Board of Pediatrics.

Technical Approach: Participants will first receive a one-hour skills-review lecture. Then, during a period of approximately four hours, participants will receive instruction on PALS procedures with live, fully anesthetized animals. Two goats will be used per session with five to six students per goat. One instructor will be present for every 6 students. Under the supervision of the Instructor, the students will perform the following PALS skills: venous cut down, percutaneous arterial line placement, central venous access, intraosseous needle placement, diagnostic peritoneal lavage, needle thoracostomy, tube thoracostomy, Swan-Ganz catheterization (demonstration in one goat, only), needle cricothyroidotomy (after euthanasia) and surgical cricothyroidotomy (after euthanasia).

Progress: Laboratory training was conducted in June and July of 1995 and successful results were achieved.



# Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: T-94-05 Status: Ongoing

Title: Training of Animal Care Specialists (91T) in Clinical Procedures and Techniques for the Care of Military Working Dogs

Start date:	Estimated completion date:
Principal Investigator: MAJ Larry Carpenter, VC	Facility: Lackland Air Force Base, Texas
Department/Service: 94th Medical Detachment, FSH TX	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To allow Animal Care Specialists to gain practical experience in clinical and emergency procedures. Hands-on training in MOS related subjects is needed to provide the necessary practice to achieve proficiency in day-to-day clinical duties as well as training for successful completion of the Self Development Test (SDT).

Technical Approach: Soldier's manual and Trainer's guides will be available to technicians with a description of task and list of specific learning objectives of each task. There will be simulations where the study will be presented with a scenario in which the patient is supposed to have sustained the injury or supposed to be suffering the condition listed. Student will be responsible to taking corrective action as outlined in the reference. This will be similar to the use of moulage casualties in mass casualty exercises.

Progress: An annual review was requested but has not been received. The exact status of this protocol is not known.

# Detail Summary Sheet

Date: 15 Nov 95 Protocol Number: T-95-01 Status: Ongoing

Title: Advanced Anesthetic Skills Laboratory Using a Porcine Model

Start date: 12 Dec 94	Estimated completion date:
Principal Investigator: CPT Samuel C. Sayson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): MAJ Paul D. Mongan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To provide anesthesiologists with clinical experience in the use of anesthesia equipment designed for field medical conditions. To train anesthesia residents in techniques of specialized airway management, neurophysiologic monitoring, and chronic pain management that are germane to the practice of anesthesia.

Technical Approach: Anesthesia will be induced and swine will be placed in dorsal recumbency and the ventral abdomen and thorax will be clipped. A femoral cutdown will be performed to expose the femoral artery and vein. The femoral artery will be cannulated for monitoring mean arterial pressure. The femoral vein will be cannulated and connected to IV solution of lactated Ringers at a rate of 5-10mg/k/hr. Anesthesia will be monitored throughout the entire procedure.

Progress: We have had difficulty staffing this protocol and are trying to reorganize so we can continue to train our residents on the use of the field anesthesia machines used in combat.

Date: 16 Oct 95 Proj No: SWOG 7804

Status: Ongoing

Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Therapy will follow the schema outlined in the protocol

Progress: One patient remains on study. Study is closed for new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 7808 Status: Ongoing

Title: Combined Modality Treatment for Stages III and IV. Hodgkin's Disease  
MOPP # 6.

Start Date FY 79	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 13	
Patients Remaining on Study: 6	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Six patients remain on the study. This study is closed to new patient accrual. However, it will remain open for follow up purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 7827 Status: Ongoing

Title: Combined Modality Therapy for Breast Carcinoma, Phase III.

Start Date FY 80

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Breast Carcinoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 61

Patients Remaining on Study: 33

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone. 3) To compare the disease-free interval and recurrent rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-three patients remain on the study. This study is closed to new patient accrual. However, it will remain open for follow up purposes.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8216/38 Status: Completed

Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date FY 85

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Cancer, Bladder

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Patients Remaining on Study: 0

Date of Periodic Review 16 Oct 95 Results Completed

Objective(s): 1) To compare the effectiveness of intravesical BCG immunotherapy with intravesical adriamycin chemotherapy with respect to disease-free interval and two-year recurrence rate. 2) To compare the toxicity of topical immunotherapy and chemotherapy. 3) To obtain experience regarding disease-free interval and the recurrence rate in patients who develop tumor recurrence and are then crossed over to the alternative treatment arm.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The study is complete. Data is being analyzed. There are no patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8229/30      Status: Completed

Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Solidation.  
Evaluation ..... Phase II

Start Date    FY 83	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    18	
Date of Periodic Review    16 Oct 95    Results    Completed	

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma. 2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission. 3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy with Vincristine.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is complete. Data is being analyzed. There are no patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8294 Status: Ongoing

Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer.

Start Date FY 83

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Breast Node Negative

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 33

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. 2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size. 3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Nineteen patients remain on the study. This study is closed to new patient accrual, open for follow up purposes only.



# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8313    Status: Ongoing

Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

Start Date    FY 84	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    9	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP). 2) To compare the effect of these two adjuvant therapies on survival. 3) To compare the relative toxicity of the two therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Three patients remain on the study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8326/27 Status: Ongoing

Title: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To compare the effectiveness of three different drug combinations using high dose Ara-C alone or high dose Ara-C in combination with m-AMSA or Mitoxantrone for remission induction in relapsed adult leukemias including both acute non-lymphocytic leukemia, chronic granulocytic during accelerated or blastic phase, as well as untreated secondary acute leukemias. 2) To monitor the side effects of the above combination chemotherapy schedules.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8393 Status: Ongoing

Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma.

Start Date FY 84

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Melanoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To determine the safest excision margins around the primary melanoma. 2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy). 3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Three patients remain on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8507    Status: Ongoing

Title: Maintenance versus no Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III.

Start Date    FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    12	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare the effectiveness of intravesical and percutaneous BCG immunotherapy given on a maintenance versus a no maintenance schedule with respect to disease free interval and rate of tumor recurrence in patients with transitional cell carcinoma of the bladder. 2) To assess the toxicity of maintenance and no maintenance BCG immunotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Seven patients remain on this study. Study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8509 Status: Ongoing

Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II.

Start Date FY 86

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Adenocarcinoma, Prostate

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 8  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To assess the antitumor activity of Menogaril in patients with advanced adenocarcinoma of the prostate. 2) To define the qualitative toxicities of menogaril administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients remain on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8515 Status: Ongoing

Title: Evaluation of Menogaril in Non-Hodgkin's Lymphoma, Phase II.

Start Date FY 88

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Non-Hodgkin's, Lymphoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To determine the response rate and response duration for favorable and unfavorable histology Non-Hodgkin's lymphoma (NHL) treated with Menogaril. 2) To define the qualitative and quantitative toxicities of Menogaril administered in a phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of non-Hodgkin's lymphoma with at least one site of bi-dimensionally measurable disease. Patients must have failed and recovered from potentially curable treatment. Patients with a cumulative dose of Adriamycin > 250 mg/m<sup>2</sup> are not eligible for this study. Allowable prior chemotherapy depends on disease type. Patients will be stratified according to histology: unfavorable histology NHL vs favorable histology NHL. Therapy will follow the schema outlined in the study protocol.

Progress: One patients remains on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8516 Status: Ongoing

Title: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBom vs MACOP-B in Patients with Intermediate or High-Grade Non-Hodgkin's Lymphoma.

Start Date FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkin's lymphoma, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To compare in a randomized Group-wide setting the complete response rate, response duration and survival of patients with intermediate and high-grade non-Hodgkin's lymphoma treated with one of four combination chemotherapy regimens: CHOP, m-BACOD, ProMACE-CytaBOM, or MACOP-B. 2) To compare the toxicities of each regimen in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Eight patients remain on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8520 Status: Completed

Title: Cis-Diamminedichloroplatinum II: Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II.

Start Date FY 87

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Carcinoma, epidermoid

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 0  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To determine the response rate in patients with advanced epidermoid carcinoma of the penis treated with cis-platinum, methotrexate, and bleomycin. 2) To evaluate the toxicity of this three-drug combination.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This study is closed to new patient accrual, open for followup purposes only.



# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8590    Status: Ongoing

Title: Phase III Study to Determine the Effect of Combining Chemotherapy With Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck.

Start Date    FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    6	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To test whether the addition of chemotherapy to surgery and radiotherapy prolongs disease-free survival and survival between the two study groups. 2) To test whether the addition of chemotherapy to surgery and radiotherapy increases local control rates at the primary site and/or the cervical neck nodes. 3) To determine if the patterns of failure have been changed with the addition of chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8591 Status: Ongoing

Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma of colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): To assess the effectiveness of levamisole alone and levamisole plus 5-fluorouracil as surgical adjuvant regimens for resectable colon cancer by comparison with untreated controls.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Six patients remaining on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8598    Status: Ongoing

Title: Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup.

Start Date    FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    2	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. 2) To determine if the patterns of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8600 Status: Ongoing

Title: A Randomized Investigation of High Dose versus Standard Dose Cytosine Arabinoside With Daunorubicin in Patients With Acute Non-Lymphocytic Leukemia, Phase III.

Start Date FY 87

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Leukemia, acute, non-lymphocytic

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 5  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose Cytosine Arabinoside and Daunorubicin or high-dose Cytosine Arabinoside and Daunorubicin. 2) To compare the durations of complete remission and of disease-free survival among patients who each receive one of three combinations of induction and consolidation regimens. 3) To determine the comparative toxicities of these three programs of induction and consolidation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8621    Status: Ongoing

Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III.

Start Date    FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    1	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare initial combined chemo-hormonal therapy with initial hormonal therapy with respect to survival. 2) To compare initial chemo-hormonal therapy using tamoxifen with that using DES with respect to survival. 3) A secondary goal is to compare combined chemo-hormonal therapy with initial hormonal therapy with respect to response in patients with measurable disease.

Technical Approach: Patients must have clinical or histologic confirmation of recurrent or disseminated breast cancer, with tumor positive for estrogen receptor or progesterone receptor. Patients with completely dissected disease or with a life threatening visceral disease will be ineligible. Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on study. This study is closed, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 8624 Status: Ongoing

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma

Start date:

Estimated completion date:

Principal Investigator:  
Timothy J. O'Rourke, COL, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Hematology/Oncology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 3

Periodic review date: 16 Oct 95 Review results:

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: The study is closed to new patient entry, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8692      Status: Completed

Title: Therapy in Premenopausal Women with advanced, ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex: Phase III, Intergroup.

Start Date    FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    0	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare the time to treatment failure and survival of medical castration using Zoladex with surgical castration in premenopausal women with advanced, ER + or PgR + breast cancer. 2) To compare the response rate of the two treatments. 3) To assess the response rate to surgical castration in patients failing to respond to or relapsing on Zoladex, and the response rate to Zoladex in patients failing to respond to or relapsing on surgical castration. 4) To compare toxicities of medical castration and surgical castration. 5) To assess the value of post-treatment hormone levels (LH, FSH and estradiol) in predicting response to medical castration.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Closed to new patient accrual. Open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 8697 Status: Ongoing

Title: Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF vs Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation of Maintenance Therapy with CMF(P)TH or CMFH Intergroup.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 1  
Periodic review date: 16 Oct 95 Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8710 Status: Ongoing

Title: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, Advanced Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To compare the survival of those patients with locally advanced bladder cancer treated with cystectomy alone to those treated with M-VAC followed by cystectomy in a randomized Phase III neoadjuvant trial. 2) To quantify the "tumor downstaging" effect of neoadjuvant M-VAC in patients with locally advanced bladder cancer.

Technical Approach: All patients must have histologically proven diagnosis of T<sub>2</sub>-T<sub>4a</sub>, N<sub>0</sub>, M<sub>0</sub> transitional cell carcinoma of the bladder without mixed histology. All patients must have adequate kidney, liver, and bone marrow function, a performance status of 0-1, and be judged potentially curable. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for patient accrual. One new patients was enrolled this year.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8711 Status: Completed

Title: A Study of Reproductive Function in Patients with Testicular Cancer.

Start Date FY 88

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Cancer, Testicular

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 95 Results Completed

Objective(s): 1. To evaluate the natural history of seminal fluid and hormonal parameters noted in Stage A testicular cancer patients treated by orchiectomy alone.

2. To evaluate the effects of a) orchiectomy plus platinum based combination chemotherapy or radiation therapy and b) retroperitoneal node dissection on the seminal fluid and hormonal parameters of Stage A, B, or C testicular cancer patients.

3. To estimate the median time to return to ejaculatory function following orchiectomy and retroperitoneal node dissection.

4. To study the effect of testicular cancer on sexual/reproductive functioning.

Technical Approach: Each patient must have histologically proven diagnosis of testis cancer for which he has undergone an orchiectomy. Patients must be registered within three weeks of their surgery. Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient accrual There are no patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8733 Status: Ongoing

Title: Evaluation of Operable Bladder Cancer Patients with Pre-Operative Irradiation + 5-FU Alone, Phase II, a Pilot Study for Patients Ineligible for SWOG-8710.

Start Date FY 88

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian Thompson, MAJ, MC

Key Words:  
Cancer, Bladder

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) Operable Patients: To evaluate the complete downstaging rate in patients with bladder cancer who are treated with pre-operative 5-FU/radiation. to assess the efficacy of treating patients with no histologic evidence of residual tumor following irradiation and 5-FU with additional irradiation and 5-FU without cystectomy. To assess the efficacy of treating patients who are not free of disease after initial treatment with 5-FU/radiation with radical cystectomy. 2) Inoperable Patients: To estimate the response rate of patients treated with 5-FU and radiation. To assess the qualitative and quantitative toxicities of this regimen in the treatment of bladder cancer.

Technical Approach: Patients must have primary or recurrent bladder cancer confined to the pelvis and no evidence of spread beyond the regional lymph nodes at or below the level of the bifurcation of the iliac vessels. Patients with prior inactive malignancies are eligible. Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8736 Status: Ongoing

Title: Treatment of Localized Non-Hodgkin's Lymphoma: comparison of Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To establish the complete response rate (CR%), CR duration, survival and toxicity of chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) (eight cycles) versus CHOP (three cycles) plus radiation therapy in a cooperative group setting for patients with localized diffuse large cell lymphoma (DLC). 2) To determine if the difference in CR rates of combined treatment (less chemotherapy alone translates into longer survival with less toxicity. 3) To determine if subgroups (based on location, histology, age, stage) have significant prognostic importance with regard to CR%, time to progression, survival and toxicity. 4) To establish CR%, time to progression and survival for localized histologies other than diffuse large cell lymphoma.

Technical Approach: All patients must have biopsy proven Stage I or IE or non-bulky Stage II or IIE non-Hodgkin's lymphoma. Patients must have intermediate or high grade histology other than lymphoblastic lymphoma. No prior chemotherapy or radiation therapy is allowed. Patients with known AIDS syndrome or HIV associated complex are not eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on study. This study remains open for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8737 Status: Ongoing

Title: Phase III AZQ 24-Hour Infusion Versus BCNU for Adult High Grade Gliomas.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Gliomas, high-grade

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the activity of 24-hour infusion AZQ versus a BCNU control for adult, high grade, supratentorial gliomas. Primary endpoints for evaluation will be survival and time to progression. Secondary endpoints, when evaluable, will be partial and complete response rates as determined by contrast enhanced CT scan. Identification of a 50% increase in survival over control is sought. 2) To develop a data base on current surgical practices with protocol patients and to study further the prevalence and management of pulmonary toxicity from BCNU.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients remain on study. This study is closed to new patient accrual. Open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8792    Status: Ongoing

Title: Phase III Study of Alfa-nl (Wellferon™) as Adjuvant Treatment for Resectable Renal Cell Carcinoma.

Start Date    FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, renal cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    2	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): To assess in a controlled fashion the effectiveness of interferon alfa-nl (Wellferon™) as a surgical adjuvant in patients with renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. Ongoing. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8793 Status: Ongoing

Title: Randomized Phase III Evaluation of Hormonal Therapy versus Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To determine the time to progression and survival, in patients with histologically confirmed Stage D1 prostate cancer following prostatectomy and pelvic lymphadenectomy treated immediately with hormonal therapy. 2) Determine whether the effects of early hormone therapy on local control of D1 prostate cancer.

Technical Approach: Patients must have histologically confirmed diagnosis of adenocarcinoma of the prostate (not including "endometroid" carcinoma). Patients must have pathologic D1 disease. Histological confirmation of pelvic node involvement is required for a patient to be considered to have Stage D1 disease. Confirmation must be obtained by formal pelvic node dissection.

Progress: Two patients remain on this study. Ongoing. This study is closed to new patient accrual open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8794 Status: Ongoing

Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Carcinoma, Prostate

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 21

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare in a randomized study, the disease-free survival rates in completely resected patients with pathologic stage C (T3N0M0) carcinoma of the prostate assigned to be treated with adjuvant external beam radiotherapy to that in patients assigned to receive no adjuvant therapy. 2) To assess the qualitative and quantitative toxicities of patients with pathologic stage C (T3N0M0) carcinoma of the prostate when treated with external beam radiotherapy.

Technical Approach: Patients must have undergone radical prostatectomy and pelvic lymphadenectomy with a histologically proved diagnosis of pathologic stage C (T3N0M0) carcinoma of the prostate. Patients must be able to begin treatment within 16 weeks after radical prostatectomy. Therapy will follow the schema outlined in the protocol.

Progress: Twenty-one patients remain on study. Study remains ongoing.



# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8795      Status: Ongoing

Title: Randomized Prospective Comparison of Bacillus Calmette-Guerin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III.

Start Date    FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, Bladder Superficial, Transitional Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    4	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): The overall objective of this protocol is to compare the efficacy and toxicity of two commonly used intravesical treatments for recurrent transitional cell carcinoma. The treatments to be evaluated are Mitomycin-C (MMC), and Tice substrain of Bacillus Calmette-Guerin (BCG).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Four patients remain on study. Ongoing. This study is closed to new patient accrual. Open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8809 Status: Ongoing

Title: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy With ProMACE-MOPP (Day 1-8) in Patients With Low Grade Malignant Lymphomas.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Lymphomas, malignant, low grade

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy + radiation therapy, to those who receive induction therapy alone. 2) To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MOPP (Day 1-8). 3) To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Six patients remain on study. Ongoing for patient accrual and followup purposes.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8814 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Breast, Receptor Positive

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. 2) To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Ten patients remain on the study. Study continues for patient accrual and followup.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8819 Status: Ongoing

Title: Central Lymphoma Repository Tissue Procurement Protocol.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Lymphoma, central  
Tissue, repository

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 1  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To acquire fresh snap-frozen lymphoma tissue to establish a central lymphoma tissue repository. 2) To establish a standard set of procedures for routine acquisition, banking, and study of lymphoma tissues within the cooperative group. 3) To use repository tissue to establish clinical correlations via presently activated phenotyping studies and future projected molecular studies assessing specimen DNA and RNA status. 4) To determine if pretreatment phenotype or genotype predict patient outcome with respect to complete response rate, time to progression, and survival using prospective trial designs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study continues for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8851 Status: Ongoing

Title: Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer --Intergroup.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor-Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (Z + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. 2) To compare the relative toxicities of these 3 regimens. 3) To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8854 Status: Completed

Title: Prognostic Value of Cytometry Measurements of Breast Cancer DNA from Postmenopausal Patients with Involved Nodes and Receptor Positive Tumors: A Companion Protocol to SWOG 8814.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Breast

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 5  
Date of Periodic Review 16 Oct 95 Results Completed

Objective(s): 1) To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG-8814. 2) To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There are no patients being followed. Study has been completed.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8855      Status: Ongoing

Title: A Flow Cytometry Companion Protocol to All Southwest Oncology Group Head and Neck Cancer Protocols Utilizing Chemotherapy as Initial Treatment.

Start Date    FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    0	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data at this time. Study is ongoing.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8892 Status: Ongoing

Title: A Study of Radiotherapy With or Without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Nasopharyngeal

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 1  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the complete response rate, time to treatment failure, overall survival and pattern of recurrence. 2) To assess the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on study. Study is ongoing.



# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8894 Status: Ongoing

Title: A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D<sub>2</sub> Prostate Cancer.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 32	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): To compare bilateral orchiectomy + flutamide versus bilateral orchiectomy alone according to: 1) Survival, 2) Progression free survival, 3) Qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Sixteen patients remain on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8895 Status: Completed

Title: Phase III Study of the role of Cricopharyngeal Myotomy in the Treatment of Dysphagia following Major Head and Neck Surgery.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 95 Results Completed	

Objective(s): 1) The objective of this study is to test the concept that cricopharyngeal myotomy performed in conjunction with the resection of a tumor involving the base of tongue or supraglottic larynx or hypopharynx will increase the frequency of patients with normal swallowing function at six months.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients being followed. Study has been completed.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8897 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients, and a Natural History Follow-up Study in Low-Risk, Node Negative Patients (Intergroup).

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Breast, Node Negative

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 34

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare disease-free survival (DFS) and overall survival(s) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. 2) To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. 3) To compare the relative toxicity of the therapies. 4) To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. 5) To evaluate the disease free survival and survival of low risk invasive breast cancer determined by receptor status, tumor size and % of S phase treated by local therapy only.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-two patients remaining on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 8899 Status: Ongoing

Title: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Low-Dose Leucovorin Plus 5-FU Plus Levamisole Following Curative Resection in Selected Patients with Duke's B or C Colon Cancer.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, Colon, Duke's B/C

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 19

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To independently assess the effectiveness of 5-FU + low-dose Leucovorin, 5-FU + high dose Leucovorin 5-FU + Levamisole and 5-FU + low-dose Leucovorin + Levamisole as surgical adjuvant therapy for resectable colon cancer

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Thirteen patients remaining on study. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 8917    Status: Ongoing

Title: 5-Fluorouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II Pilot.

Start Date    FY 90

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Cancer, colorectal

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period:    0

Total Number of Subjects Enrolled to Date:    8

Date of Periodic Review    16 Oct 95    Results    Continue

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further study. 2) To evaluate the qualitative and quantitative toxicities of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. Ongoing. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8925      Status: Ongoing

Title: Evaluations of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane or Cisplatin + BP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma.

Start Date FY 89

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Carcinoma, Metastatic Adrenal Cortical

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To evaluate the response and response duration of patients with:

- adrenocortical carcinoma treated with combination chemotherapy consisting of cisplatin and etoposide, and
  - of those who receive mitotane after progression on the above chemotherapy (if no prior treatment with mitotane).
- 2) To evaluate the qualitative and quantitative toxicities of these therapies. 3) To evaluate and compare tumor morphology of patients with this rare tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8931      Status: Ongoing

Title: Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer.

Start Date FY 90

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Breast, cancer

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16 week multi-drug chemotherapy regimen. 2) To compare toxicities of adjuvant CAF and a 16 week multi-drug regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients remain on study. Ongoing. This study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8942      Status: Completed

Title: High Dose Etoposide, Cyclophosphamide and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Non-Hodgkin's Lymphoma.

Start Date FY 90

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Lymphoma, non-hodgkin's

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 2  
Date of Periodic Review 16 Oct 95 Results Completed

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Non-Hodgkin's lymphoma treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant. 2) To assess the non-hematopoietic toxicities of these regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients being followed. Study has been completed.



# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8947      Status: Ongoing

Title: Central Lymphoma Serum Repository Protocol.

Start Date    FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    1	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. 2) To utilize the Southwest Oncology Group clinical database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8949      Status: Ongoing

Title: A Randomized Comparison of Nephrectomy Followed by Introna vs Introna Alone in Patients with Advanced Renal Cell Carcinoma

Start Date FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Carcinoma, Advanced  
Renal Cell

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To evaluate and compare the survival and response rates of patients with metastatic renal cell carcinoma receiving nephrectomy followed by Interferon Alpha-2b (Introna) vs. Interferon Alpha-2b (Introna) alone.  
2) To evaluate morbidity and mortality associated with adjuvant nephrectomy in metastatic renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on the study. Study ongoing. No reportable data is available at this time.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8952      Status: Ongoing

Title: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid.

Start Date    FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Advanced Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    4	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. 2) To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. 3) To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Three patients remain on study. Study ongoing. No reportable data at this time.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8954      Status: Ongoing

Title: Evaluation of the L-17M Protocol in the Management of Patients with Lymphoblastic Lymphoma, Phase II, Pilot.

Start Date FY 90

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Lymphoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 0  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To assess the response rate and response duration of lymphoblastic lymphoma treated with the L-17M protocol. 2) To assess the qualitative and quantitative toxicities of the L-17M protocol administered in a Phase II study. 3) To assess the immunophenotypic characteristics of adult lymphoblastic lymphoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing. Study remains open for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8990      Status: Ongoing

Title: Combined Modality Treatment for Resectable Metastatic Colorectal Carcinoma to the Liver: Surgical Resection of Hepatic Metastases in Combination with Continuous Infusion of Chemotherapy.

Start Date FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Carcinoma, Colorectal  
Metastatic to liver

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0  
Total Number of Subjects Enrolled to Date: 0  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To study the incidence of recurrence and time to recurrence in patients with 1-3 hepatic metastases treated with resection alone versus resection and continuous infusion of 5-FU into the systemic venous system and FUDR into the hepatic artery.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8993      Status: Ongoing

Title: Phase II Study of High Dose Melphalan with Hemopoietic Stem Cell Support and GM-CSF in Refractory Multiple Myeloma.

Start Date FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Myeloma, Multiple

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2  
Total Number of Subjects Enrolled to Date: 3  
Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To evaluate therapeutic efficacy and toxicity of high dose melphalan (HDM 200mg/M<sup>2</sup>) in patients with multiple myeloma (MM) resistant to VAD and alkylating agents followed by autologous hemopoietic stem cell support (marrow and/or blood) and GM-CSF administration. 2) To assess the feasibility of measuring multi-drug resistance in this group of patients. 3) To determine the feasibility of conducting such high dose therapy in a multi-institutional setting such as SWOG as a prelude to future trials for patients earlier in the disease course.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients were enrolled during this reporting period. Study remains ongoing for patient enrollment.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 8994      Status: Ongoing

Title: Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794.

Start Date FY 90

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Ian M. Thompson, MAJ, MC

Key Words:  
Prostate, adenocarcinoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare these primary aspects of quality of life, according to treatment assignment: 1.11) Treatment specific symptoms; 1.12) Physical functioning; 1.13) Emotional functioning.

2) To compare three secondary quality of life variables, according to treatment assignment: 1.21) General symptoms; 1.22) Global perception of quality of life; 1.23) Social functioning.

3) The comparison of quality of life measurements between treatment arms will complement the analysis of survival data for patients registered to SWOG-8794 and become a critical consideration if no difference is demonstrated in survival between the treatment arms.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Fourteen patients remain on study. Study remains open for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9000      Status: Completed

Title:    Biomarkers of Colorectal Cancer Prognosis.

Start Date    FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Colorectal Cancer

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period:    0

Total Number of Subjects Enrolled to Date:    0

Date of Periodic Review    16 Oct 95    Results    Completed

Objective(s): 1) To evaluate if aneuploidy in Dukes B or C colon cancers as determined by flow cytometric analysis of DNA content has independent prognostic significance for survival or disease free survival in patients enrolled on SWOG-8591. 2) To evaluate if aneuploidy in colon cancers is predictive of patients who benefitted from adjuvant therapy with levamisole or 5-FU plus levamisole by increased survival or disease free survival in SWOG-8591.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients on followup. Study is completed.



# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9003      Status: Ongoing

Title: Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 95      Results      Continue	

Objective(s): 1) To estimate response rates and survival in patients with Waldenstrom's Macroglobulinemia (WM) receiving fludarabine, with stratification according to whether they have had prior therapy. 2) To define prognostic factors that may relate to response, time to progression and overall survival, separately for newly diagnosed and previously treated patients. 3) To estimate the associated hematologic and non-hematologic toxicities.

Technical Approach: As outlined in the protocol schema.

Progress: One patient remains on study. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9005      Status: Ongoing

Title: Double Blind Randomized Trial of the Anti-Progestational Agent Mifepristone in the Treatment of Unresectable Meningioma, Phase III

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review    16 Oct 95      Results      Continue	

Objective(s): 1) To compare daily oral mifepristone vs placebo with respect to time to treatment failure in patients with unresectable meningioma. 2) To further evaluate the tolerance of long term oral mifepristone.

Technical Approach: As outlined in the protocol schema.

Progress: There are no patients on followup and there is no reportable data. Study remains ongoing for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9007      Status: Ongoing

Title:    Cytogenetic Studies in Leukemia Patients, Ancillary.

Start Date    FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    1	
Total Number of Subjects Enrolled to Date:    5	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. 2) To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. 3) To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients being followed and there is no reportable data available at this time. Study remains open for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9008      Status: Ongoing

Title: Trial of Adjuvant Chemoirradiation After Gastric Resection for Adenocarcinoma.

Start Date    FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, Gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    1	
Total Number of Subjects Enrolled to Date:    2	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoirradiation after gastric resection.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients remain on this study. There is no reportable data available at this time.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9011      Status: Ongoing

Title: High Dose Etoposide, Cyclophosphamide, and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Hodgkin's Disease.

Start Date    FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Bone marrow transplant, hodgkins disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    3	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Hodgkin's disease treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant.

2) To assess the non-hematopoietic toxicities of these regimens in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on this study. Study remains ongoing.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9013      Status: Ongoing

Title: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery vs Surgery alone for Patients with Local Regional Disease, Phase III-Intergroup.

Start Date    FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous carcinoma, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    1	
Total Number of Subjects Enrolled to Date:    4	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, vs pre- and post- operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. 2) To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. 3) To compare the local and distant control rates with the two approaches and to define the pattern of failure. 4) To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Three patients remain on study. There is no reportable data available at this time.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9019      Status: Ongoing

Title: A Phase III, Randomized, Prospective Comparison Between Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIa (Positive Mediastinal Nodes) and Selected Stage IIIb (No Malignant Effusion) Non-Small Cell Lung Cancer.

Start Date    FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    2	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) Assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (N2-positive) and selected IIIb non-small cell lung cancer. 2) Evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing. One patient remains on this study.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9021      Status: Completed

Title:    Post-Operative Radiotherapy for Single Brain Metastases, Phase II.

Start Date    FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Metastases

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period:    0

Total Number of Subjects Enrolled to Date:    0

Date of Periodic Review    16 Oct 95    Results    Continue

Objective(s): 1) To evaluate the effectiveness of whole brain radiation therapy given after complete resection of single brain metastasis from systemic cancer. 2) To compare complete surgical resection plus postoperative whole brain radiation therapy to complete resection alone, with respect to survival, site of recurrence, cause of death, and quality of life. 3) To evaluate the use of Quality of Life Questionnaire specific for CNS malignancies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients on this study at this time. Study has been completed.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9023 Status: Ongoing

Title: Cytogenetic and Flow Cytometric Analysis of Solid Tumors: Renal Cell Carcinoma: A Companion Study to SWOG-8949

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will followed the schema outlined in the protocol.

Progress: Study is still ongoing and open for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9024 Status: Ongoing

Title: A Pilot Study of Combined Modality Therapy in T3, 4; No, Mo  
Adenocarcinoma of the Prostate, Phase II.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To evaluate the likelihood of complete response of T3, T4; No Mo prostate cancer to prolonged venous infusion of 5-fluorouracil in combination with external beam radiation therapy. 2) To evaluate the safety and toxicity of pelvic irradiation in combination with prolonged venous infusion of 5-fluorouracil at a dose of 200mg/m2/day.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Eight patients remain on this study. Study remains ongoing for further patient enrollment.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9028 Status: Completed

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD to VAD/Verapamil/Quinine for Induction with Crossover to VAD/Verapamil/Quinine for VAD Induction Failures; (2) Alpha-2B Interferon or Alpha-2B Interferon Plus Prednisone for Remission Maintenance.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, Multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapamil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients enrolled on study. Study has been completed and data accrual achieved.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9031 Status: Ongoing

Title: A Double Blind Placebo Controlled Trial of Daunomycin and Cytosine Arabinoside With or Without rhg-CSF in Elderly Patients With Acute Myeloid Leukemia, Phase III.

Start Date FY 92

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:  
Acute myeloid Leukemia

Key Words:

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the complete response rates and durations of survival in patients aged 56 or older with acute myeloid leukemia (AML) when treated with standard doses of Cytosine Arabinoside (Ara-C) and Daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhg-CSF). 2) To assess the frequency and severity of toxicities of the two treatment regimens. 3) To compare the duration of neutropenia and thrombocytopenia; the total of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhg-CSF). 4) To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on this study. Study continues with patient followup.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 9032    Status: Ongoing

Title: A Controlled Trial of Cyclosporine As a Chemotherapy-Resistance Modifier In Blast Phase-Chronic Myelogenous Leukemia, Phase III.

Start Date    FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: cyclosporine, Chemotherapy-Modifier
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    0	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare the duration of survival in patients with chronic myelogenous leukemia (CML) in blast phase, when treated with either chemotherapy (Ara-c/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA). 2) To estimate the frequency of P-glycoprotein expression and its association with blast lineage and prognosis. 3) To compare the frequency and severity of toxicity of the two treatment regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is ongoing. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9034 Status: Completed

Title: Phase III Study of Three Intensive Post-Remission Therapies in Adult Acute Non-Lymphocytic Leukemia: comparison of Autologous bone Marrow Transplantation, Intensive Chemotherapy and Allogenic Bone Marrow Transplantation

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results:

Objective(s):

Technical Approach: Therapy will follow the treatment schema outlined in the protocol.

Progress: Study is closed. There were no patients enrolled.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 9035    Status: Ongoing

Title: Randomized Trial of Adjuvant Immunotherapy with an Allogenic Melanoma Vaccine for Patients with Intermediate Thickness Node, Negative Malignant Melanoma (T3N0M0) Phase III.

Start Date    FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Allogenic Melanoma Vaccine
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    0	
Date of Periodic Review    16 Oct 95    Results    Continue	

Objective(s): 1) To compare disease-free survival and overall survival between patients with T3N0M0 malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. 2) To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3N0M0 malignant melanoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients currently enrolled on study. There is no reportable data available.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9038 Status: Completed

Title: Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer Phase II Pilot.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Lung Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 16 Oct 95 Results Completed	

Objective(s): 1) To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in advanced non-small cell lung cancer. 2) To evaluate the qualitative toxicities of this regimen administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There are no patients remaining on study for followup.



# Detail Summary Sheet

Date: 16 Oct 95		Proj No: SWOG 9039		Status: Completed	
Title: Evaluation of Quality of Life in Patients with Stage D2 Cancer of the Prostate Enrolled on SWOG-8894.					
Start Date FY 91			Est Comp Date:		
Principal Investigator: Timothy J. O'Rourke, LTC, MC			Facility: Brooke Army Medical Center		
Dept/Svc: Department of Medicine/Oncology			Associate Investigators: Ian M. Thompson, MAJ, MC		
Key Words: Cancer, Prostate					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: 0					
Total Number of Subjects Enrolled to Date: 22					
Date of Periodic Review 16 Oct 95 Results Completed					

Objective(s): The Cancer Control intervention study measures quality of life in patients with advanced carcinoma of the prostate. Specifically, it is a companion protocol for SWOG-8894. Treatment of Stage D2 Carcinoma of the Prostate Comparing Orchiectomy +/- Flutimide.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients on followup. Study is complete.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9040 Status: Ongoing

Title: Intergroup Rectal Adjuvant Protocol, A Phase III Study.

Start Date FY 91

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Carcinoma, Rectal

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): The objective of the proposed study is to determine the relative efficacy of: 5-FU, 5-FU and leucovorin, 5-FU and levamisole and 5-FU, leucovorin and levamisole when combined with pelvic radiation therapy in the treatment of Stages B-2 and C rectal cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on this study. Study is closed to new patient accrual, open for followup purposes only.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9041 Status: Ongoing

Title: Chemoprevention of Recurrent Adenomas and Second Primary Colorectal Carcinoma. A Phase III Pilot Study.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results:

Objective(s): 1) To investigate the ability of the Southwest Oncology Group to enroll sufficient numbers of patients with early stages of CRC with the intent of preventing subsequent adenomas or new primary carcinomas. New investigators, such as gastroenterologists and surgeons who treat these early malignancies, will be identified, who can participate and are willing to enroll patients in this study. 2) To monitor compliance in pill intake (the dose taken), the drop-out rate and the completion rate of yearly surveillance colonoscopy. 3) To monitor toxicities of calcium supplementation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients on study. Status remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9043 Status: Completed

Title: Phase III Randomized Trial of Beta Carotene vs Placebo in Prevention of Second Primaries in Stages I and II Head and Neck Cancer.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients enrolled in this study.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9058 Status: Completed

Title: A Phase II Trial of Intravenous Vinorelbine (Navelbine) in Previously Untreated Extensive Small Cell Lung Carcinoma.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Vinorelbine, Lung Carcinoma
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 95 Results Completed	

Objective(s): 1) To assess whether vinorelbine (Navelbine) given as a weekly intravenous infusion produces objective clinical responses in patients with previously untreated extensive small cell lung cancer. 2) To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous vinorelbine (Navelbine).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients enrolled on study or on followup. Study is completed.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9059 Status: Ongoing

Title: Phase III Comparison of Standard Radiotherapy, versus Radiotherapy plus Simultaneous Cisplatin, Versus Split Course Radiotherapy plus Simultaneous Cisplatin and 5-Fluorouracil, in Patients with Unresectable Squamous Cell Carcinoma of the Head and Neck.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Ongoing

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. This is a new study. There is no reportable data. Study is ongoing.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9061 Status: Ongoing

Title: A Phase III Study of Conventional Adjuvant Chemotherapy Versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation Versus Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in patients with Stage II and III Breast Cancer at High Risk of Recurrence.

Start Date FY 92

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Breast Cancer

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To compare the sites and rates of recurrence, disease-free survival and overall survival, and toxicity of adjuvant chemotherapy (CAF) with adjuvant chemotherapy plus high-dose therapy with cyclophosphamide and ThioTEPA with autologous marrow infusion in patients with breast cancer with 10 or more positive lymph nodes. 2) To compare the efficacy and toxicity of 3 different infusion schedules of GM-CSF. 3) To prospectively evaluate the incidence and degree of occult marrow contamination due to breast cancer cells at the time of study entry and following CAF chemotherapy by analyzing samples of marrow using a panel of monoclonal antibodies specific for breast cancer. 4) To document the changes in psychosocial function that occur during treatment on the two regimens and to compare post-treatment recovery of psychosocial function.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Three patients are enrolled on study. Study is ongoing.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9106 Status: Ongoing

Title: Evaluation of Two High Dose Chemotherapy Regimens with Autologous Bone Marrow Support for Selected Patients with Advanced Ovarian Cancer, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One adverse event was reported in August 1994. Otherwise, there is no reportable data. Study remains ongoing for patient accrual.



# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 9108    Status: Ongoing

Title: A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia.

Start Date    FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Chronic Lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    1	
Date of Periodic Review    16 Oct 95    Results    Completed	

Objective(s): 1) To compare in previously untreated CLL patients the response rates and progression free survival. 2) To determine whether the quality of life is superior using any of the three regimens. 3) To determine whether Fludarabine Phosphate and chlorambucil are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they were initially randomized.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There are no patients remaining on study.

# Detail Summary Sheet

Date: 16 Oct 95

Protocol Number: SWOG 9109

Status: Ongoing

Title: Neoadjuvant Zoladex and Flutamide in Bulky and Non-Bulky Clinical Stage C Carcinoma of the Prostate, Phase II

Start date:

Estimated completion date:

Principal Investigator:  
Timothy J. O'Rourke, COL, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Hematology/Oncology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 5

Periodic review date: 16 Oct 95 Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are four patients remaining on study. Study remains ongoing for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95    Proj No: SWOG 9110    Status: Completed

Title:    A Phase II Evaluation of Didemnin B In Central Nervous System Tumors.

Start Date    FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC; MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Central Nervous Tumors, Didemnin B
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:    0	
Total Number of Subjects Enrolled to Date:    0	
Date of Periodic Review <u>24 Oct 94</u> Results <u>Continue</u>	

Objective(s): 1) evaluate the likelihood of response in order to assess whether didemnin B should be advanced to further studies and, 2) evaluate the qualitative and quantitative toxicities of didemnin B.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There are no patients currently on followup.

# Detail Summary Sheet

Date: 16 Oct 94 Proj No: SWOG 9111 Status: Ongoing

Title: Phase III Study of Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, Metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alfa-2b as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. 2) To evaluate the efficacy and tolerance of long-term Interferon alfa-2b at 3 MU/d (SC TIW) as an adjuvant to increase the disease-free survival and overall survival of patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is ongoing. Currently there is one patient enrolled on study.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9119 Status: Ongoing

Title: Primary Chemotherapy of Poor Prognosis Soft Tissue Sarcomas Phase II, Pilot.

Start Date FY 92

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:  
Soft Tissue Sarcomas

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 95 Results Continue

Objective(s): 1) To evaluate the efficacy of primary chemotherapy, wide surgical resection, adjuvant chemotherapy and radiotherapy on local control, metastasis free survival and overall survival. 2) To evaluate the utility of tumor response to primary chemotherapy as an indicator of local and systemic disease control in high grade soft tissue sarcoma. 3) To evaluate the toxicity of primary chemotherapy, surgery, adjuvant chemotherapy and radiation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is ongoing. Currently there are no patients enrolled on this study.

# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9124 Status: Ongoing

Title: Evaluation of Edatrexate in Patients with Relapsed or Refractory Germ Cell Tumors.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson MD
Key Words: Refractory, Germ Cell Tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 95 Results Continue	

Objective(s): 1) To assess the rate and duration of response to Edatrexate.  
2) Evaluate patterns of toxicity (qualitative and quantitative) in patients treated with Edatrexate Therapy will follow the schema outlined in the protocol.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9129      Status: Ongoing

Title: Phase III Randomized Study of All-Trans Retinoic Acid Versus Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia.

Start Date    FY	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Non-Small Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 16 Oct 95    Results    Ongoing	

Objective(s): 1) To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubicin in patients with previously untreated APL. 2) To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as Induction Therapy in APL. 3) To determine the value of maintenance therapy with TRA.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is ongoing. Currently there is one patient enrolled on this study. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95	Proj No: SWOG 9130	Status: Ongoing
Title: Smoking Cessation for Early Bladder Cancer Patients Using a Combined Brief Physician Message and Cancer Information Service (CIS) Counseling Approach		
Start Date	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 16 Oct 95 Results Completed		

Objective(s): This is a two-arm randomized trial to compare the efficacy of a brief, two-staged smoking cessation intervention with "usual care" among early stage bladder cancer patients. The primary objective of this study is to assess the efficacy of a combined physician-initiated, Cancer Information Service (CIS) reinforced quite smoking intervention compared with "usual care" in terms of the one year smoking quite rate in newly diagnosed patients with early stage bladder cancer.

Technical Approach: As outlined in the protocol schema.

Progress: Study is completed. There are no patients on followup.



# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9133      Status: Ongoing

Title: Randomized Trial of Subtotal Nodal Irradiation Versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III.

Start Date

Est Comp Date:

Principal Investigator:  
Timothy J. O'Rourke, LTC, MC

Facility:  
Brooke Army Medical Center

Dept/Svc:  
Department of Medicine/Oncology

Associate Investigators:

Key Words:

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review      16 Oct 95      Results      Continue

Objective(s): 1) The primary objective is to compare the progression-free and overall survivals of non-laparotomized patients with clinical Stage I-IIA Hodgkin's Disease treated with subtotal nodal irradiation (3600-4000cGy) alone or subtotal nodal irradiation plus 3 cycles of doxorubicin and vinblastine.

Technical Approach: As outlined in the protocol schema.

Progress: There are no patients remaining on study. Study ongoing for patient accrual. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: SWOG 9136      Status: Ongoing

Title: Biologic Parameters in Soft Tissue Sarcomas: A Companion Study to Select Southwest Oncology Group Clinical Trials with Soft Tissue Sarcoma Patients.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95      Review results: \_\_\_\_\_

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data. There are no patients on study.  
 Study remains ongoing for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95	Proj No: SWOG 9139	Status: Ongoing
Title: Adjuvant Therapy of Primary Osteogenic Sarcomas, Phase II.		
Start Date FY 92	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:	
Key Words: Sarcoma, Osteogenic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 0		
Date of Periodic Review 16 Oct 95 Results Continue		

Objective(s): To estimate the time to treatment failure and survival rate of the three drug combination Adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. 2) To evaluate histopathologic tumor necrosis following preoperative Adriamycin, cisplatin, and ifosfamide. 3) To assess the feasibility of determining histopathologic tumor necrosis in a cooperative group setting. 4) To assess the influence of clinical prognostic variables on disease outcome. 5) To assess the toxicity of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are no patients currently enrolled on study. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9140      Status: Ongoing

Title: Phase II Study of Oral Biopiramine Combined with Intravesical Bacillus Calmette-Guerin (Tice) in Patients with Carcinoma in situ of the Bladder.

Start Date

Est Comp Date:

Principal Investigator:

Timothy J. O'Rourke, LTC, MC

Facility:

Brooke Army Medical Center

Dept/Svc:

Department of Medicine/Oncology

Associate Investigators:

Key Words:

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 95      Results      Continue

Objective(s): 1) Assess the response probability in order to determine whether the combination of oral bropiramine and BCG should be advanced to further studies and 2) Evaluate the qualitative and quantitative toxicities of the combination oral bropiramine and BCG.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled to date. There is no data to report.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9142 Status: Ongoing

Title: Evaluation of Gallium Nitrate Continuous Infusion Therapy for Advanced Bladder Carcinoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results:

Objective(s): 1) Assess the efficacy and feasibility of utilizing gallium nitrate in patients who have progressed following cytotoxic chemotherapy with advanced or recurrent urothelial tract tumors. 2) Evaluate the toxicity of gallium nitrate in this group of patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data. One patient has been enrolled.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9147 Status: Ongoing

Title: Evaluation of Tamoxifen in Desmoid Tumors, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the response rate of fibromatosis to treatment with tamoxifen. 2) To assess the clonality in "informative" female patients (i.e., females heterozygous for the genetic locus) utilizing a molecular probe for an x-linked enzyme.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9148      Status: Completed

Title: A Phase II Study of Cisplatin Preceded by a 12 Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (ARA-C) for Patients with Untreated, Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 16 Oct 95      Results      Continue	

Objective(s): 1) To evaluate the response rate of this program in patients with extensive-stage small cell lung cancer (ENSCLC). 2) To evaluate the response rate of this program in patients with extensive-stage small cell lung cancer (ESCLC). 3) To assess the qualitative and quantitative toxicities of this regimen in each patient population.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled on study to date. Study has been completed.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9149 Status: Ongoing

Title: A Phase II Study of Cisplatin Preceded by a 12-Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (Ara-C) for Adult Patients with Malignant Gliomas

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results:

Objective(s): 1) To evaluate the 6-month survival rate of this 3-drug program in patients with malignant gliomas (both anaplastic astrocytomas and glioblastomas) recurrent or refractory to surgery, radiotherapy, and/or nitrosoureas. 2) To evaluate the qualitative and quantitative toxicities of this regimen in this patient population. 3) To evaluate the response rate to this regimen for this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There have been no patients enrolled to date. There is no reportable data.



# Detail Summary Sheet

Date: 16 Oct 95 Proj No: SWOG 9152 Status: Completed

Title: Prediction of Recurrence and Therapy Response in Advanced Germ Cell Tumors by DNA Flow Cytometry.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 15 Oct 95 Results Completed	

Objective(s): 1) To determine the proliferative activity and presence of aneuploidy within paraffin-embedded histopathologic specimens from patients with advanced disseminated (poor prognosis) GCT. 2) To correlate proliferative activity and aneuploidy with clinical features including response to therapy, relapse-free survival, and overall survival in patients entered on ECOG protocol EST 3887/SWOG 8997/CALGB 8991; Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin plus Etoposide with either Bleomycin or Ifosfamide.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There are currently no patients enrolled on this study. Study has been completed.

# Detail Summary Sheet

Date: 16 Oct 95      Proj No: SWOG 9158      Status: Ongoing

Title: Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (STAGE IV)

Start Date

Est Comp Date:

Principal Investigator:

Timothy J. O'Rourke, LTC, MC

Facility:

Brooke Army Medical Center

Dept/Svc:

Department of Medicine/Oncology

Associate Investigators:

Key Words:

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Oct 95      Results      Continue

Objective(s): 1) To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. 2) To further define the qualitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: As outlined in the protocol schema.

Progress: There are no patients enrolled on this study. Study remains ongoing.

# Detail Summary Sheet

Date: 16 Oct 95

Protocol Number: SWOG 9201

Status: Ongoing

Title: "Phase III Trial to Preserve the Larynx: Induction Chemotherapy and Radiation Therapy versus Concomitant Chemotherapy and Radiation Therapy versus Radiation."

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): The primary endpoint is survival with preservation of laryngeal function. In achieving this overall goal the following outcomes will be assessed: 1) Length of disease-free survival with a preserved larynx. 2) Length of overall survival. 3) Evaluation of tumor response at the completion of chemotherapy prior to RT for induction chemotherapy (Arm 1) and at the completion of RT for concomitant treatment (Arm 2). 4) Patterns of relapse: local and regional recurrence and distant metastasis. The incidence of second primary tumors. 5) Incidence of adverse effects: acute and late. 6) Concomitant morbidity of neck dissection and/or laryngeal salvage surgery. 7) QOL for patients with laryngeal preservation versus patients requiring salvage laryngectomies. 8) To evaluate QOL outcomes between patients receiving radiation therapy alone and those receiving adjuvant therapy.

Technical Approach: As outlined in the protocol schema.

Progress: Currently there is one patient enrolled on study. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Protocol Number: SWOG 9205      Status: Ongoing

Title: Central Prostate Cancer Serum Repository Protocol

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 18  
 Periodic review date: 16 Oct 95      Review results: Continue

Objective(s): 1) To store serum of patients with cancer of the prostate entered onto clinical trials conducted by the Southwest Oncology Group Genitourinary Committee. 2) To provide the serum of the above patients entered on Southwest Oncology Group studies for specific clinical-laboratory investigations (e.g. evaluation of a new marker) outlined on separate Southwest Oncology Group protocols approved by the Genitourinary Committee Tumor Biology Subcommittee.

Technical Approach: As outlined in the protocol schema.

Progress: Fourteen patients remain on this study. Study is ongoing for patient followup and accrual.

# Detail Summary Sheet

Date: 16 Oct 95                      Protocol Number: SWOG 9210                      Status: Ongoing

Title: "A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction: (2) Randomization of Prednisone Dose Intensity for Remission Maintenance"

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95      Review results: \_\_\_\_\_

Objective(s): 1) To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. This will be evaluated in terms of response  $\geq$  50% regression), overall and relapse-free survival, and P-glycoprotein expression prior to therapy at the end of induction therapy in relation to the induction therapy arm. 2) To evaluate the chemosensitizing potential of quinine to reverse drug resistance in myeloma patients randomized to VAD-P induction who fail to achieve at least 25% regression with chemotherapy alone. 3) To compare the value of alternate day prednisone (10 mg) versus 50 mg of prednisone for remission maintenance for patients proven to achieve at least 25% regression. The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization of maintenance therapy.

Technical Approach: As outlined in the protocol schema.

Progress: There are currently no patients on study. Study is ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9216 Status: Ongoing

Title: "A Randomized Phase III Study of CODE Plus Thoracic Irradiation Versus Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer, (NCIC CTG)."

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: 1) overall survival; 2) time to disease progression; 3) response rate; 4) response duration; 5) quality of life.

Technical Approach: As outlined in the protocol schema.

Progress: One patient remains on study. Study is ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95      Protocol Number: SWOG 9217      Status: Ongoing

Title: "Chemoprevention of Prostate Cancer with Finasteride (Proscar), Phase III Intergroup."

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): LTC Ian M. Thompson, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 116  
 Total number of subjects enrolled to date: 275  
 Periodic review date: 16 Oct 95      Review results: \_\_\_\_\_

Objective(s): To test the difference in the biopsy-proven prevalence of carcinoma of the prostate between a group of participants treated with finasteride and a group treated with placebo for seven years.

Technical Approach: As outlined in the protocol schema

Progress: Two-hundred twenty-eight patients remain on study. Study is ongoing for patient data accrual and followup.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9218 Status: Completed

Title: "Measurement of O<sup>6</sup> MGMT in Patients with High Grade Primary Brain Tumors Treated with Radiation Therapy and BCNU, Ancillary Study"

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): To explore the prognostic significance of O<sup>6</sup>-Methylguanine-DNA Methyltransferase (O<sup>6</sup> MGMT) in predicting survival among patients with high grade gliomas receiving BCNU and radiation therapy, and to develop a preliminary definition of good risk/poor risk categories based on low/high levels of O<sup>6</sup> MGMT issue levels.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients entered on this study. There is no reportable data.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9219 Status: Ongoing

Title: A Phase II Evaluation of Interleukin-4 (IL-4) in Patients with Non-Hodgkin's Lymphoma or Hodgkin's Disease

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the response rate of refractory low grade non-Hodgkin's lymphoma, refractory intermediate or high grade non-Hodgkin's lymphoma and refractory Hodgkin's disease treated with interleukin-4. 2) To assess the qualitative and quantitative toxicities of interleukin-4 administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9221 Status: Ongoing

Title: Phase III Double-Blind Randomized Trial of 13-Cis Retinoic Acid (13-CRA) to Prevent Second Primary Tumors (SPTs) in Stage I Non-Small Cell Lung Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate the efficacy of 13-cis-retinoic acid (13-CRA) in reducing the incidence of SPTs in patients who have been treated for Stage I non-small cell lung cancer with complete surgical resection. 2) To evaluate the qualitative and quantitative toxicity of 13-CRA in a daily administration schedule. 3) To compare the overall survival of patients treated with 13-CRA vs. patients treated with placebo.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9228 Status: Completed

Title: Evaluation of Interleukin-4 (IL-4) in Disseminated Malignant Melanoma, Phase II.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To evaluate the response rate of disseminated malignant melanoma treated with interleukin-4. 2) To assess the qualitative and quantitative toxicities of interleukin-4 administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There is no reportable data. No patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9230 Status: Completed

Title: Evaluation of Interleukin-4 (IL-4) in Disseminated Renal Cell Adenocarcinoma, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results: 0

Objective(s): 1) To evaluate the response rate of disseminated or recurrent renal cell adenocarcinoma treated with interleukin-4. 2) To assess the qualitative and quantitative toxicities of interleukin-4 administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9237 Status: Ongoing

Title: Evaluation of Topotecan in Refractory and Relapsing Multiple Myeloma, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate the response rate for refractory myeloma treated with topotecan. 2) To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II Study. 3) To measure topoisomerase levels in multiple myeloma cells.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9242 Status: Ongoing

Title: Evaluation of Taxotere in Small Cell Lung Carcinoma, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate the efficacy, as measured by the response rate, of Taxotere given every three weeks by intravenous infusion to patients with previously untreated extensive small cell lung cancer. 2) To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous Taxotere.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. There is no reportable data available.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9246 Status: Ongoing

Title: A Phase II Evaluation of Taxol in Patients with Relapsed Non-Hodgkin's Lymphoma or Relapsed Hodgkin's Disease

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the response rate of relapsed low grade non-Hodgkin's lymphoma, relapsed intermediate or high grade non-Hodgkin's lymphoma and relapsed Hodgkin's disease treated with taxol. 2) To assess the qualitative and quantitative toxicities of taxol administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patients remains on followup. There is no reportable data available.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9248 Status: Completed

Title: A Phase II Trial of Paciltaxel (TAXOL) in Patients with Metastatic Refractory Carcinoma of the Breast

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. 2) To evaluate the clinical response rate of paciltaxel in patients with refractory carcinoma of the female breast. 3) To evaluate the qualitative and quantitative toxicities of paciltaxel in a Phase II study.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled this year. Study is closed to further patient accrual. There are no patients on followup.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9250 Status: Ongoing

Title: Phase III Intergroup Prospectively Randomized Trial of Perioperative 5-FU after Curative Resection, Followed by 5-FU/Levamisole for patients with Colon Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To determine if adjuvant therapy with one week of continuous 5-FU given within 24 hours of a curative colon resection followed by 12 months of 5-FU/levamisole is effective in prolonging the disease free interval and increasing survival in patients with Dukes' B3 or C colon cancer, when compared to patients who are treated with 5-FU/levamisole only. 2) To establish within ECOG a Central Tissue Repository for paraffin blocks and a frozen tissue bank.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is completed. There is no reportable data. There are no patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9252 Status: Ongoing

Title: Prospective Randomized Trial of Postoperative Adjuvant Therapy in Patients with Completely Resected Stage II and Stage IIIa Non-Small Cell Lung Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To determine if combination chemotherapy plus thoracic radiotherapy is superior to thoracic radiotherapy alone in prolonging survival in patients with completely resected Stage II and Stage IIIa non-small cell lung cancer. 2) To determine if combination chemotherapy plus thoracic radiotherapy is superior to thoracic radiotherapy alone in preventing local recurrence in patients with resected Stage II and Stage IIIa non-small cell lung cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. Study continues for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9300 Status: Ongoing

Title: A Randomized Phase II Evaluation of All Trans-Retinoic Acid (ATRA) with Interferon-Alfa 2a (IFN-alfa 2a) or All Trans-Retinoic Acid with Hydroxyurea (HU) in Patients with Newly Diagnosed Chronic Myelogenous Leukemia in Chronic Phase.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 1	
Periodic review date: 16 Oct 95 Review results: Continue	

Objective(s): 1) To estimate whether treatment of chronic myelogenous leukemia (CML) in chronic disease phase using all trans-retinoic acid (ATRA) in combination with either hydroxyurea (HU) or interferon-alfa 2a (IFN) is sufficiently effective based on either hematologic or cytogenetic response, to justify its investigation in Phase III trials.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient remains on study. Study still ongoing for patient accrual. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95      Protocol Number: SWOG 9303      Status: Ongoing

Title: "Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer"

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95      Review results: Continue

Objective(s): 1) The primary goal of this study will be to determine whether 5FU, levamisole and radiation therapy results in superior overall survival when compared to 5FU and levamisole without radiation therapy in the management of patients with completely resection pathologic stage T<sub>4b</sub>N<sub>0</sub>-2 colon cancer and selected patients with T<sub>3</sub>N<sub>1,2</sub> colon cancer. 2) Disease-free survival, patterns of failure and toxicity will also be evaluated. If radiation therapy improves disease-free survival, patterns of failure and toxicity will also be evaluated. If radiation therapy improves disease-free survival or freedom from local failure without improving survival consideration may be given to further evaluation of RT in subsequent trials. The additional of radiation therapy will only be declared to have definitive patient benefit, however, if it results in superior survival.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled on study this year. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9304 Status: Ongoing

Title: Postoperative Evaluation of 5-FU by Bolus Injection versus 5-FU by Prolonged Venous Infusion Prior To and Following Combined Prolonged Venous Infusion Plus Pelvic XRT Versus Bolus 5-FU Plus Leucovorin Plus Levamisole Prior to and Following Combined Pelvic XRT plus Bolus 5-FU Plus Leucovorin in Patients with Rectal Cancer, Phase III.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the effectiveness of 5-FU by bolus injection vs 5-FU by prolonged venous infusion given prior to and following combined pelvic XRT + protracted venous infusion (PVI) vs 5-FU by bolus injection plus LV plus LEV given prior to and following combined pelvic XRT plus bolus 5-FU plus LV in the treatment of modified Astler-Collier Stages B2, B3 and C rectal cancer. This will be evaluated in terms of survival and relapse-free survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open for patient accrual. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9306 Status: Ongoing

Title: Conservative Treatment of Adenocarcinoma of the distal Rectum: Local Resection Plus Adjuvant 5-FU/Radiation Therapy, a Phase II Intergroup Study

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To determine whether the survival of patients with T<sub>1</sub> and T<sub>2</sub> adenocarcinoma of the rectum who have been treated with limited sphincter sparing surgery is comparable to that of historical controls treated with radical surgery (abdominoperineal resection). 2) To determine whether the survival of patients with T<sub>3</sub> adenocarcinoma of the rectum who have been conservatively treated is comparable to that of historical controls treated with abdominoperineal resection. 3) To assess the loco-regional recurrence rate of rectal cancer patients treated with conservative surgery as a function of stage (T<sub>1</sub>/T<sub>2</sub> or T<sub>3</sub>).

Technical Approach: This is a new study. There is a no reportable data.

Progress: There have been no patients entered on study during this reporting period. Study remains ongoing for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9307 Status: Ongoing

Title: Extended Administration of Oral Etoposide and Oral Cyclophosphamide for the Treatment of Poor Prognosis Extensive Disease Small Cell Lung Cancer, Phase II Pilot.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in poor prognosis extensive disease small cell lung cancer. 2) To evaluate the qualitative and quantitative toxicities of this regimen administered in a Phase II study. 3) To investigate possible correlations between peak and trough plasma etoposide levels versus complete response, toxicity, and survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There have been no patients enrolled during this reporting period. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9308 Status: Completed

Title: Randomized Trial Comparing Cisplatin with Cisplatin Plus Intravenous Navelbine in the Treatment of Previously Entreated, Stage IV Non-Small Cell Lung Cancer Patients

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To compare the effect of cisplatin alone with that of intravenous Navelbine plus cisplatin on tumor response rate, survival and time to treatment failure with patients with Stage IV non-small cell lung carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient was enrolled during this reporting period. There is no reportable data. There are no patients on followup.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9312 Status: Ongoing

Title: Phase II Evaluation of Cisplatin & 5-FU & Radiation Therapy in patients with Locally Advanced/Inoperable Bladder Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the response rate and the feasibility of utilizing cisplatin + 5-FU + radiation therapy in patients with locally advanced/inoperable carcinoma of the bladder. 2) To assess the qualitative and quantitative toxicities of this combination. 3) To perform a preliminary study to assess: (a) The potential role of DNA ploidy analysis as a predictor of response to combined therapy in locally advanced bladder cancer. (b) The potential value of suppressor gene expression analysis (p53 and retinoblastoma gene) as prognostic indicator.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9310 Status: Ongoing

Title: An Intergroup Phase II Combined Modality Treatment of Primary Central Nervous System Lymphoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the rate of tumor response to combination chemotherapy prior to the start of radiation. 2) To compare survival using a combined modality approach to historical controls using radiotherapy alone 3) To assess the long-term toxicity of this regimen. 4) Based upon the response rate and survival of patients enrolled in this study, to consider a randomized trial to compare chemotherapy alone vs chemotherapy plus radiation in an effort to reduce the morbidity of cranial irradiation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9313 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemotherapy with High Dose Cyclophosphamide plus Doxorubicin (AC) versus Sequential Doxorubicin followed by Cyclophosphamide (A->C) in High-Risk Breast Cancer Patients with 0-3 Positive Nodes (Intergroup)

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>2</u>	
Total number of subjects enrolled to date: <u>2</u>	
Periodic review date: <u>16 Oct 95</u> Review results: <u>Continue</u>	

Objective(s): 1) To compare disease-free survival (DFS), overall survival (S), and toxicity of high-risk primary breast cancer patients with negative axillary lymph nodes or with one to three positive nodes treated with adjuvant high-dose chemotherapy with doxorubicin plus cyclophosphamide (AC), versus high-dose sequential chemotherapy with doxorubicin followed by cyclophosphamide (A->C). 2) To obtain tumor tissue for biologic studies. The details of these biologic studies will be described in a companion protocol or protocols to be developed through the intergroup mechanism.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Two patients remain on study. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9314 Status: Ongoing

Title: Biologic Factors Predicting Response to Tamoxifen in Patients Registered to SWOG 8228, Ancillary

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9320 Status: Ongoing

Title: A Phase II Study of ProMACE-CytaBOM with Trimethoprim Sulfamethoxazole, Zidovudine (AZT) and Granulocyte Colony Stimulating Factor (G-CSF) in Patients with AIDS-related Lymphoma.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the response rate of AIDS-related lymphomas treated with the ProMACE-CytaBOM regimen. 2) To assess the toxicities of the ProMACE-CytaBOM regimen in patients who have AIDS-related lymphomas.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9321 Status: Ongoing

Title: Standard Dose Versus Myeloablative Therapy for Previously Untreated Symptomatic Multiple Myeloma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To perform a randomized trial, in newly diagnosed patients with symptomatic multiple myeloma (MM), of standard therapy versus myeloablative therapy, in order to examine whether the greater tumor cytoreduction effected by intensive therapy and manifested by higher incidence of complete remission translates into extended overall survival and progression-free survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: One patient was enrolled during this reporting period and will continue on study. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9223 Status: Ongoing

Title: Laboratory/Clinical Correlative Studies in Non-Small Cell Lung Cancer:  
Ancillary Study to SWOG 9252

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To determine the incidence of K-ras and P53 mutations; assess Group A blood antigen and EGF receptor levels; evaluate neuroendocrine markers on keratin-negative, mucin-negative tumors by electron microscopy; and assess P105 and Factor 8 levels in patients with completely resected Stage II or IIIA NSCLS. 2) Correlate these results with patient histology, TNM stage, time to relapse, and survival. 3) Establish within ECOG a central tissue repository.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for data collection and analysis.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9325 Status: Ongoing

Title: An Evaluation of the In-Vivo Mechanism of Interferon Alfa-2b in the Context of ECOG Trial E1690 (SWOG 9111) Comparing Interferon Administration for 1 Year at High Dosage to Interferon Long-Term Therapy at Lower Dosage as Prophylaxis for High Risk Lymph Node-Metastatic Cutaneous Melanoma, Ancillary.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) Analysis of the in vivo immunomodulatory effects of IFN alfa-2b upon host lymph node and/or blood lymphocyte effector cell function and phenotype obtained. 2) Analysis of the modulatory anti-proliferative and enzyme inductive effect of in vitro IFN alfa-2b exposure upon autologous tumor cells (in those subjects from whom lymph node tumor has been harvested) 3) Correlation of host immunomodulatory effects, tumor cell surface antigen modulation and susceptibility to host effector cell function, and serological response to autologous tumor with disease outcome in reference to IFN alfa-2b against autologous or HLD-matched allogeneic tumor cells will be (a) Cytotoxicity; (b) Cytokine modulation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for data accrual.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9328 Status: Ongoing

Title: Autologous Bone Marrow Transplantation for Patients with Acute Myeloid Leukemia Beyond First Remission: A Randomized Trial of Post-Transplant Therapy with Interleukin-2 versus Observation, Phase III

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the disease-free survival and overall survival of patients with acute myeloid leukemia (AML) in untreated first relapse (Rel 1) or second complete remission (CR2) treated by autologous bone marrow transplantation (ABMT), using marrow obtained while in CR1 or CR2 and who then receive either post-transplant therapy with interleukin-2 (IL-2) or not further treatment. 2) To assess the frequency and severity of toxicity associated with post-transplant IL-2 therapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9332 Status: Completed

Title: Phase III Trial of Adriamycin Versus Taxol Versus Taxol Plus Adriamycin Plus G-CSF in Metastatic Breast Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To compare the objective response rate and time to progression of single-agent Adriamycin, single-agent Taxol, and the combination of Adriamycin and Taxol in patients with previously untreated metastatic breast cancer. 2) To compare the toxicity of Adriamycin, Taxol, and Adriamycin and Taxol given in combination. 3) To determine whether Taxol and Adriamycin exhibit crossover resistance to each other. 4) To compare the quality of life of patients who have received Taxol, Adriamycin, or the combination of Taxol and Adriamycin as first-line therapy for metastatic breast cancer. 5) To compare the quality of life of patients who have received Taxol or Adriamycin as second-line therapy. 6) To evaluate the relation of steady state Taxol levels to therapeutic response and toxicity.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is closed to patient accrual. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: SWOG 9333 Status: Ongoing

Title: A Randomized Controlled Trail of Mitoxantrone and Etoposide versus Daunomycin and Cytosine Arabinoside as Induction Therapy in Patients Over Age 55 With Previously Untreated Acute Myeloid Leukemia, Phase III.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the complete remission (CR) rate, duration of survival and duration of relapse-free survival (time from CR until relapse or death) for patients aged 56 or older with acute myeloid leukemia (AML) treated with daunomycin (daunorubicin, DNR) and cytosine arabinoside (Ara-C) or with mitoxantrone (Mito) and etoposide (VP-16). 2) To assess the frequency and severity of toxicities and the durations of neutropenia, thrombocytopenia, and first hospitalization associated with the two induction chemotherapy regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continued for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9336 Status: Ongoing

Title: A Phase III Comparison Between Concurrent Chemotherapy Plus Radiotherapy, and Concurrent Chemotherapy Plus Radiotherapy, and Concurrent Chemotherapy Plus Radiotherapy Followed by Surgical Resection of Stage IIIA (N2) Non-Small Cell Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, median, and long-term (2-year, 5-year) survival compared to the same chemotherapy plus standard radiotherapy alone for patients with Stage IIIa (N2-positive) non-small cell lung cancer. 2) Evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is closed to patient accrual. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9339 Status: Ongoing

Title: Evaluation of Topotecan in Esophageal Carcinoma, Part II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate the response rate of esophageal carcinoma treated with topotecan. 2) To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. There is no reportable data.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9340 Status: Ongoing

Title: A Phase III Randomized Study of Radiotherapy with or with Budr Plus Procarbazine, CCNU, and Vincristine (PCV) for the Treatment of Anaplastic Astrocytomas

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): To compare the efficacy of treatment with radiotherapy and PCV chemotherapy versus radiotherapy plus Budr and PCV chemotherapy. The endpoints for this evaluation will be: 1. Time to disease recurrence or progression, measured from the first day of treatment. 2. Response rates and disease stabilization rates. 3. Survival time, measured from th first day of treatment. 4. Activity level as determined by Karnofsky Performance Status.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9341 Status: Ongoing

Title: A Phase II High Dose Ifosfamide (HDI) with Mesna and Granulocyte-Colony Stimulating Factor (rhg-CSR) in Unresectable Malignant Mesothelioma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the activity of high-dose ifosfamide and mesna with recombinant human G-CSF (rhg-CSF) in patients with unresectable malignant mesothelioma. 2) To evaluate the toxicity pattern of high-dose ifosfamide/mesna/rhg-CSF given according to this outpatient schedule.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9343 Status: Ongoing

Title: Evaluation of Combined Androgen Suppression and Fixed Schedule Suramin in Patients with Newly Diagnosed Metastatic Prostate Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) The primary objective of this pilot study is to assess the feasibility of fixed schedule suramin plus combined androgen suppression (orchiectomy plus flutamide, or LHRH agonist plus flutamide) in a cooperative group setting in patients with newly diagnosed Stage D2 prostate cancer. Feasibility evaluation is based on an assessment of the magnitude of suramin-related neurotoxicity or treatment interruption of four weeks or more. 2) Progression-free survival and survival will also be estimated.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. There is no reportable data.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9347 Status: Ongoing

Title: Phase III Comparison of Tamoxifen vs Tamoxifen with Ovarian Ablation in Premenopausal women with Axillary Node - Negative Receptor - Positive Breast Cancer  $\leq$  cm. Intergroup

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the disease-free survival, overall survival, and toxicity of treatment in hormone receptor-positive, premenopausal women with axillary lymph node-negative breast cancer measuring 3 cm or less given adjuvant therapy with tamoxifen alone or tamoxifen with ovarian ablation. 2) To obtain tumor tissue from these patients for future biologic studies of relevance to this patient population. 3) To compare menopausal symptoms, sexual function and quality of life in patients receiving tamoxifen alone with patients receiving tamoxifen plus ovarian ablation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9348 Status: Ongoing

Title: Evaluation of the Standard BCNU/DTIC/Cisplatin/Tamoxifen Regimen in Disseminated Malignant Melanoma, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Completed

Objective(s): 1) To estimate the response rate of the combination of BCNU/DTIC/Displatin/tamoxifen with patients with disseminated malignant melanoma in order to select the appropriate regimen for combination with alpha-interferon in a future Phase III trial. 2) To accurately determine the toxicities of this drug combination in order to issues as feasibility in a future Phase III trial.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. Study is completed. There are no patients on followup.

# Detail Summary Sheet

Date: 16 Oct 95      Protocol Number: SWOG 9349      Status: Ongoing

Title: A Randomized Phase II Trial of CHOP with G-CSF Support or ProMACE-CytaBOM with G-CSF Support for Treatment of Non-Hodgkin's Lymphoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95      Review results: Continue

Objective(s): 1) To evaluate the effectiveness of the dose intense CHOP chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and prednisone) with G-CSF support and the dose intense ProMACE-CytaBOM chemotherapy regimen (cyclophosphamide, doxorubicin, etoposide, prednisone, cytosine, arabinoside, bleomycin, vincristine, methotrexate and leucovorin) with G-CSF support in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. The effectiveness of the regimens will be based on the estimate of the complete response rate, the time to treatment failure, and ultimately overall survival. 2) To assess the toxicities and side effects associated with the regimens. 3) A secondary objective is to further utilize the central serum and tissue repositories enabling clinicopathologic correlations with the results of studies on the material collected (see companion studies, SWOG 8219, 9245 and 8947.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9401 Status: Ongoing

Title: A Controlled Phase III Evaluation of 5-FU Combined with Levamisole and Leucovorin as Surgical Adjuvant Treatment Following Total Gross Resection of Metastatic Colorectal Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): Current Mayo/NCCTG research protocol (89-46-51) for patients with high risk stage II (selected Dukes' B2, B3) and stage III colon cancer is comparing the standard 5FU plus levamisole combination with a new three drug regimen of 5FU plus levamisole combination with a new three drug regimen of 5FU plus levamisole plus leucovorin. Both regimens are given for a period of one year. Patients are also being randomly assigned to either 12 months of therapy (the standard) or 6 months of therapy (the experimental approach) to address the secondary question of optimal treatment duration.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9402 Status: Ongoing

Title: Phase III Intergroup Randomized Comparison of Radiation Alone vs Pre-Radiation Chemotherapy for Pure and Mixed Anaplastic Oligodendrogliomas

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) The primary endpoint of this trial is overall survival. 2) This study will compare time to tumor progression between the two arms. The frequency of seven  $\leq$  grade 3 toxicities will be examined. 4) This study will compare quality of life and neurologic function between the two arms. 5) This study will identify the key histopathologic criteria necessary to make the diagnosis of anaplastic oligodendroglioma and mixed oligoastrocytoma; evaluate the diagnostic and prognostic relevance of chromosomal alterations; evaluate the diagnostic and prognostic relevance of DNA ploidy and indices of proliferation including percent S and percent G2M; study the diagnostic and prognostic relevance of immunohistochemical markers of cellular function and/or glial development; and evaluate the translational relevance of tumor suppressor genes and oncogenes. These objectives will be studied utilizing the tissues and peripheral blood samples obtained from the patients entered on this trial and funded by a grant to Dr. Robert Jenkins, Pathologist and Molecular Geneticist, Mayo Clinic, Rochester, MN 55905.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9410 Status: Ongoing

Title: Doxorubicin Dose Escalation, with or without Taxol as Part of the CA Adjuvant Chemotherapy Regimen for Node Positive Breast Cancer. A Phase III Intergroup Study

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To determine whether higher doses of doxorubicin used as an adjuvant with cyclophosphamide in patients with early breast cancer will increase disease free and overall survival. 2) To determine whether the use of Taxol as a single agent after the completion of four cycles of cyclophosphamide and doxorubicin in combination will further improve disease-free and overall survival compared to cyclophosphamide and doxorubicin alone. 3) To determine whether treatment with Taxol will improve disease-free and overall survival regardless of the dose of cyclophosphamide and doxorubicin. More specifically, to determine if Taxol following standard dose cyclophosphamide and doxorubicin will be as effective or more effective than high dose cyclophosphamide and doxorubicin without Taxol. 4) To assess the toxicity of the different doses of cyclophosphamide and doxorubicin with and without Taxol using the end point of life threatening or lethal toxicity.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9412 Status: Ongoing

Title: Phase III Randomized Comparison of Maintenance Chemotherapy with Cyclophosphamide, Methotrexate, and 5-Fluorouracil vs High Dose Chemotherapy with Cyclophosphamide, Thiotepa, and Carboplatin and Autologous Bone Marrow Support for Women with Metastatic Breast Cancer who are Responding to Conventional Induction Chemotherapy

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date: 16 Oct 95 Review results: Continue	

Objective(s): 1) To compare the time to failure and overall survival in patients with metastatic breast cancer responsive to conventional-dose induction chemotherapy who are treated with high-dose chemotherapy and autologous bone marrow rescue to those treated with conventional-dose maintenance chemotherapy. 2) To compare the toxicity in patients treated with 4-6 cycles of conventional-dose chemotherapy followed by high-dose chemotherapy with autologous bone marrow rescue versus 4-6 cycles of conventional-dose induction chemotherapy followed by further conventional-dose maintenance chemotherapy. 3) To compare the relative economic costs of a prolonged course of conventional-dose chemotherapy to high-dose chemotherapy to high-dose chemotherapy and autologous bone marrow rescue in patients with metastatic breast cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9413 Status: Ongoing

Title: Phase II Treatment with Etoposide (E), Leucovorin (L), 5 Fluorouracil and Interferon Alpha 2b (I), (ELFI) + G-CSF for Locally Advanced or Recurrent Pancreatic Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9415 Status: Ongoing

Title: Phase III Randomized Trial of 5-FU/Leucovorin/Levamisole as Adjuvant therapy for High-Risk Resectable Colon Cancer, an Intergroup.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): To compare the effectiveness of bolus 5-FU, leucovorin, levamisole vs continuous infusion 5-FU, levamisole as adjuvant therapy for patients with Stage B2, C1 or C2 colon cancer. This will be measured in terms of overall survival. Disease-free survival will be a secondary endpoint.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9416 Status: Ongoing

Title: A Phase II Trial Induction Chemoradiotherapy Followed by Surgical Resection for Non-Small Cell Lung Cancer Involving the Superior Sulcus (Pancoast Tumors)

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9419 Status: Ongoing

Title: Tumor Tissue biopsy for Thymidylate Synthase Expression in Patients with Colorectal Cancer, Ancillary

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9420 Status: Ongoing

Title: Correlation of Intratumoral Thymidylate Synthase Expression with Clinical Response to 5-Fluorouracil as a Continuous Low-Dose Infusion or Intermittent High-Dose Infusion in Patients with Disseminated Colorectal Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9424 Status: Ongoing

Title: Phase II Trial of High Dose Tamoxifen Plus Cisplatin Chemotherapy in Metastatic Non-Small Lung Cancer

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results: Continue

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9426 Status: Ongoing

Title: A Phase III Trial of Flutamide Withdrawal After Patients Taking Flutamide have had Disease Progression on SWOG 8894

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the proportion of response to flutamide withdrawal in patients with metastatic hormone-refractory prostate cancer previously treated on SWOG-8994. Response shall be determined by both PSA and traditional objective criteria. 2) To estimate the time to progression after flutamide withdrawal. 3) To evaluate the pretreatment variables that predict time to progression after flutamide withdrawal.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9428 Status: Ongoing

Title: Evaluation of DNA Ploidy and p53 in Patient Registered to SWOG 8794 and SWOG 9024

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate the clinical usefulness of DNA ploidy information gained from a prostate biopsy prior to therapy by comparing it to the DNA of tumor obtained from the Stage C site (SWOG-8794), and as a predictor of outcome for patients undergoing primary radiation therapy and 5-FU treatment (SWOG-9024). 2) To compare DNA ploidy information as measured by flow cytometry (FCM) and quantitative fluorescence image analysis (QFIA). 3) To evaluate the ability of the tumor ploidy at the Stage C site to predict outcome in patients entered on SWOG-8794, in relationship to tumor progression or recurrence in those patients undergoing observation or receiving postoperative radiation therapy. 4) To evaluate p53 as a marker in the above prostate cancer patients by comparing the p53 information that is obtained by immunohistochemistry, flow cytometry, and single-strand conformational polymorphism (SSCP), and by analyzing the p53 information as a predictor of patient outcome in the following groups: a) patients being followed after radical prostatectomy; b) patients receiving radiation therapy after radical prostatectomy; c) patients undergoing 5-FU and radiation therapy as a primary treatment modality. 5) To evaluate the ploidy and p53 status of benign areas in the radical prostatectomy specimens as compared to that found in overt tumors.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient enrollment and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9429 Status: Ongoing

Title: Phase II Trial of Carboplatin and VP-16 with Concurrent Radiation for Poor-Risk Stage III Non-Small Cell Lung Carcinoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To assess the median and two-year survival and progression-free survival of poor-risk patients with Stage III non-small cell lung carcinoma treated with concurrent radiation, carboplatin and VP-16. 2) To assess the response rate and pattern of local and distant failure. 3) To assess the toxicity of this regimen in this group of poor-risk patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is closed to patient accrual, but is ongoing for follow-up of one patient remaining on study.



# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9432 Status: Ongoing

Title: Induction Chemotherapy Followed by High Dose Chemoradiotherapy with Autologous Stem Cell Rescue for Patients with Newly Diagnosed Ki67 Positive Diffuse Aggressive Lymphoma, A BMT Study, Phase II

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To evaluate in a group-wide setting the overall survival, failure-free survival, and response rates of patients with diffuse aggressive non-Hodgkin's lymphomas that are Ki67 positive ( $\leq 80\%$ ) who are treated with chemotherapy followed by transplant therapy. Transplant therapy is total body irradiation (TBI), high-dose etoposide, cyclophosphamide and peripheral blood stem cell transplant (PBSCT).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9438 Status: Ongoing

Title: Phase III total Body Irradiation, Etoposide, Cyclophosphamide and Autologous Peripheral Blood Stem Cell Transplantation Followed by Randomization to Therapy with Interleukin-2 Versus Observation for Patients with Non-Hodgkin's Lymphoma. A BMT Study.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the survival and disease-free survival of patients with non-Hodgkin's lymphoma treated with post-transplant therapy with Interleukin-2 (IL-2) or no further treatment. Transplant therapy is total body irradiation (TBI), high-dose etoposide, cyclophosphamide and peripheral blood stem cell transplant (PBSCT).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9442 Status: Ongoing

Title: A Randomized Multi-Institutional Phase III Trial of BEP and High-Dose Chemotherapy Versus BEP Alone in Previously Untreated Patients with Poor Risk Germ Cell Tumors

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To compare the efficacy of two cycles of bleomycin, etoposide, and cisplatin (BEP) Plus two cycles of high dose carboplatin, etoposide and cyclophosphamide with autologous bone marrow transplant (AuBMT) or stem cell infusion) to four cycles of BEP alone in previously untreated germ cell tumor (GCT) patients with poor risk features. 2) To compare the toxicity associated with early dose intensification with high dose chemotherapy and AuBMT/stem cells compared with standard chemotherapy of four cycles of BEP in previously untreated poor risk GCT patients. 3) To prospectively evaluate the rate of decline of serum tumor markers, human chorionic gonadotrophin (HCG) and alphafetoprotein (AFP) of patients in both arms of the study for use as post-treatment prognostic indicators. These will be correlated with complete response and survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9445 Status: Ongoing

Title: Prognostic Factor panel to Predict Preferred Therapy for Node Positive Postmenopausal Breast Cancer Patients (AF vs. Tamoxifen) (A Companion Protocol to SWOG 8814 [INT-0100, CALGB-9194, EST-4188, NCCTG-883051, NCIC-MA.9])

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): The overall objective of this study is to correlate a panel of markers with clinical outcome and responsiveness to adjuvant therapy of node positive post menopausal breast cancer patients who participated in southwest Oncology Group protocol SWOG 8814. The most important initial objective is to confirm the results of CALGB study, CALGB-8541, which suggested that c-erbB-2 expression (as detected by immunohistochemistry) is a strong predictor of the efficacy of CAF-based adjuvant chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9450 Status: Ongoing

Title: Prostate Cancer Intervention Versus Observation Trial

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) To determine the effect on prostate cancer specific mortality. 2) To determine the effect on health status. 3) To determine the effect on disease recurrences. 4) The progression-free survival, the determinants of prostate cancer progression and mortality.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 16 Oct 95 Protocol Number: SWOG 9501 Status: Ongoing

Title: A Phase II Trial of Fludarabine and Mitoxantrone (FN) for Treatment of Non-Hodgkin's Lymphoma

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 16 Oct 95 Review results: Continue

Objective(s): 1) Estimate the two-year progression-free survival rate in patients with previously untreated low-grade non-Hodgkin's lymphoma treated with fludarabine and mitoxantrone. 2) To evaluate the toxicity of fludarabine and mitoxantrone in this group of patients.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient and data accrual.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 7799 Status: Ongoing

Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies.

Start date: 25 Sep 81	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Review results: Continue

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: Recommend we keep study open. No new patients this year.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8104 Status: Ongoing

Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start date: 27 Jan 83	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words: Neuroblastoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient accrual. Three patients remain on followup with no problems. Study remains open for followup of patients.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8340 Status: Ongoing

Title: Allogenic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study.

Start date: 12 Aug 85	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC Barbara Reeb
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 22  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new entries

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherapy and fractionated total body irradiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.  
 2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.  
 3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for followup of patients only.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8600/01/02 Status: Ongoing

Title: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia in Childhood (AlinC #14) - A Pediatric Oncology Group Phase III Study.

Start date: 28 Mar 86	Est Comp Date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words: Leukemia, Lymphoid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Review results: Open/followup only

Objective(s): 1) To test the concept that intensive asparaginase (ASP) therapy designed to maintain low asparagine levels for the first six months of maintenance will improve the outcome of patients with standard risk acute lymphocytic leukemia (ALL) when added to pulses of intermediate dose methotrexate (MTX) as compared to intensification with IDM alone.  
 2) To study the effectiveness in standard risk patients of intensification with a potentially synergistic or additive drug pair, i.e. IDM plus AraC, as compared to that of intensification with IDM pulses alone.  
 3) To determine if administering a pulse of IDM + AraC at 3 week intervals during the first 4 months of complete remission in children with ALL is superior to administering the same number of IDM + AraC pulse at 23-week intervals during the first 2 years of complete remission in children with ALL with either "lower" or "higher" risk of relapse.  
 4) To obtain further information on the immediate and delayed toxicity of the continuation of chemotherapy program that incorporates these combinations of MTX and AraC or MTX and ASP in moderately high doses.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient entry. Continue followup of patients.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8625/26 Status: Ongoing

Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA, Hodgkin's Disease in Pediatric Patients.

Start date: 30 Jul 86	Est Comp date: 01 Sep 92
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words: Hodgkin's	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Review results: Continue

Objective(s): 1) To compare the effectiveness of 3 cycles of MOPP/ABVD vs 2 cycles of MOPP/ABVD plus low dose radiation therapy in terms of duration or remission and eventual survival (with one cycle = 1 course MOPP and 1 course of ABVD) in children with early stage Hodgkin's disease.

2) To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD vs MOPP/ABVD plus involved field, low dose radiation therapy.

3) To evaluate the incidence of CR after 2 cycles of MOPP/ABVD.

4) To search for prognostic factors that may correlate with duration of survival.

5) To determine the salvage rate of patients who fail to respond to 2 cycles of MOPP/ABVD or who fail to achieve a CR after completion of prescribed therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient entry. Open for followup only.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8650 Status: Ongoing

Title: National Wilms Tumor Study - 4: Stage I/Favorable or Anaplastic Histology.

Start date: 19 Dec 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words: Wilms tumor	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): To gain a better understanding of the Wilms's tumor by gathering detailed information regarding gross and histologic morphology and to correlate this information with treatment and clinical outcome.

Technical Approach: Patients will be randomized according to stage and histology.

Therapy will follow the schema outlined in the study protocol.

Progress: Study is closed to new patient entry. A total of five have been entered and are being followed.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8691 Status: Ongoing

Title: T-Cell #3 Pilot Study.

Start date: 30 Jul 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Review results: Closed to new pts

Objective(s): 1) To determine the toxicity and complications associated with the administration of this intensive chemotherapy regimen to children with T-cell leukemia and advanced state T-cell lymphoma.

2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwide T-cell study evaluating intensive L-asparaginase therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No new patients entered on study. Study remains open for followup purposes only.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8704 Status: Ongoing

Title: T-Cell #3 Protocol - A POG Phase III Study.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): 1) To estimate the disease-free survival of a multiagent chemotherapy regimen designed to be particularly effective for patients with T-cell derived lymphoid malignancies in children with advanced stage lymphoblastic lymphoma and T-cell acute lymphoblastic leukemia.

2) To determine the efficacy of adding intensive high-dose L-asparaginase to the backbone chemotherapy regimen in an attempt to improve disease-free survival.

Technical Approach: Patients <21 years and >12 months with a diagnosis of ALL, or patients age <21 years with a diagnosis of lymphoblastic lymphoma will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed. However, two patients are currently being followed.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8725 Status: Ongoing

Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA, IIIB, and IV Hodgkin's Disease in Pediatric Patients.

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine, in a randomized study, whether the addition of low dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone.

To determine whether TNRT will significantly increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone.

To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient entry. Two patients still in followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8741/42 Status: Ongoing

Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma in Children >365 Days at Diagnosis.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): To evaluate response rates and toxicity of four sequentially administered Phase II chemotherapy agents when given prior to conventional therapy in patients >365 days of age with Stage D (metastatic) neuroblastoma. The specific agents to be studied are: ifosfamide, carboplatin (CBDCA), cis-dichloro-transdihydroxy-bis-platinum (CHIP), and epirubicin.

Technical Approach: Any patient with newly diagnosed metastatic (Stage D) neuroblastoma who is >365 days and <21 years of age, who has receive no previous chemotherapy or irradiation therapy, and who has measurable disease will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study now closed for patient accrual. Two patients current in followup.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8743 Status: Ongoing

Title: Treatment in 'Better Risk' Neuroblastoma: POG Stage B (All Ages) and POG Stage C, D, and DS (VS) <365 Days.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): 1) To prospectively identify patients <365 days of age at diagnosis who will fail to achieve CR with cyclophosphamide (CYC) and Adriamycin (ADR) and delayed surgery; then to alter therapy in these patients and evaluate the CR and survival rates with alternate therapy, using cis-platinum (CDDP) and VM-26.

2) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: One patient continues on followup with no evidence of disease. Although the study has been closed to new entries, it remains open for follow-up.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8820 Status: Ongoing

Title: VP-16, AMSA+/1 5 Azacytidine in Refractory ANLL, Phase II/III.

Start date: 13 Mar 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): 1) to compare, in a randomized study, the remission rate of VP-16/AMSA versus VP-16/AMSA/5-AZA in children with recurrent or refractory acute non-lymphocytic leukemia (ANLL).

2) To determine the duration of remission, using pulses of the induction regimen as continuation therapy.

3) To study the relative toxicities of these two therapies.

Technical Approach: Patients < 21 years of age at the time initial diagnosis who have either failed to respond to induction therapy or who are in first relapse are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains ongoing for patient followup. Two patients are being followed.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8821 Status: Ongoing

Title: AML#3 Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia.

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 9  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses.

To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytosan preparative regimen and 4-hydroxycyclophosphamide (4-HC) purged marrow is effective therapy.

To compare, in a randomized study, the results of the above 2 regimens and to correlate the treatment outcome with clinical and laboratory features.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient entry. Four patients alive and being followed.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8823 Status: Completed

Title: Recombinant Alpha-Interferon in Childhood Myelogenous Leukemia, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed myelogenous leukemia (ACML) in chronic phase, and for "juvenile" chronic myelogenous leukemia (JCML) occurring within the first two decades.

Technical Approach: Eligible patients must have been < 21 years of age at the time of initial diagnosis and must not have received prior anti-neoplastic therapy. Therapy will follow the schema outlined in the study protocol.

Progress: Study is closed. No patients entered this year.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8828 Status: Ongoing

Title: Late Effects of Treatment of Hodgkin's Disease, Non-therapeutic Study.

Start date: 12 Jun 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG 8625 and 8725. In particular to focus on known sequelae of Hodgkin's disease and its treatment.

Technical Approach: All patients registered on front-line phase III POG Hodgkin's disease therapeutic studies POG 8625 and POG 8725 after the opening of this study will be eligible and must be registered on this study unless the patient or parent/guardian refuses.

Progress: Study remains open for patient accrual. No patients entered to date.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8829 Status: Ongoing

Title: A Case Control Study of Hodgkin's Disease in Childhood - A Nontherapeutic Study.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
ulative MEDCASE cost:	Estimated cumulative OMA cost: Cum

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results: Continue

Objective(s): To conduct first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children.

Technical Approach: All pediatric oncology patients, less than 15 years of age with a newly confirmed diagnosis of Hodgkin's disease are eligible. Telephone interview and administration of questionnaire will be conducted.

Progress: Study remains open. No patients entered.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8844 Status: Completed

Title: Stage D Neuroblastoma #4: Bone Marrow Transplant in the Treatment of Children > 365 Days at Diagnosis with Stage D Neuroblastoma.

Start date: 12 Dec 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): 1) To determine whether the outcome of children > 365 days with Stage D neuroblastoma who are treated at institutions offering an autologous bone marrow transplant (ABET) option to conventional therapy and who have good initial response to conventional therapy, is better than the outcome of similar children who are treated at institutions which do not offer the transplant option.

2) To evaluate the toxicities associated with this protocol.

Technical Approach: Patients >365 days and <21 years at diagnosis previously registered on POG 8741/42 who have completed post-induction evaluation and post induction surgery are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Study now closed to new patient entry. A total of three patients entered on study and are being followed.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8850 Status: Ongoing

Title: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin With or Without the Addition of Ifosfamide and Etoposide in the Treatment of Patients With Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone, Phase III.

Start date: 13 Mar 89

Estimated completion date:

Principal Investigator:  
Terry E. Pick, COL, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Pediatrics

Associate Investigator(s):  
Reginald Moore, LTC, MC

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 1

Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): To determine the event-free survival and survival of patients with Ewing's sarcoma and PNET of the bone who are treated with etoposide and ifosfamide in combination with standard therapy, and to compare their EFS and survival rates with those of patients treated with standard therapy alone.

Technical Approach: Patients <30 years of age with newly diagnosed Ewing's sarcoma and PNET of bone, or a diagnosis compatible with primitive sarcoma of bone are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient entry. One patient in followup.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 8930 Status: Ongoing

Title: A Comprehensive Genetic Analysis of Brain Tumors.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry A. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To determine prospectively the clinical significance of abnormalities of cellular DNA content, as measured by flow cytometry and to determine the clinical implications of cytogenetic abnormalities in pediatric brain tumors.

Technical Approach: Any patient with a brain tumor who has had tumor tissue submitted for study and who is subsequently registered on a POG frontline therapeutic protocol is eligible for this study.

Progress: Study remains open for patient entry.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9000 Status: Ongoing

Title: Alinc 15 Laboratory Classification Protocol for Acute Lymphoblastic Leukemia.

Start date: 17 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 13  
 Periodic review date: \_\_\_\_\_ Review results: Study remains open

Objective(s): To determine the specific subtype of leukemia in order to plan treatment.

Technical Approach: All eligible patients will undergo bone marrow aspiration followed by specific blood studies as outlined in the study protocol.

Progress: Study remains open. Three patients entered this year. Total patients entered-13.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9005 Status: Ongoing

Title: Alinc 15: Dose Intensification of Methotrexate and 6-Mercaptopurine for ALL in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 9  
 Periodic review date: Review results:

Objective(s): To determine, in a randomized trial, whether intensification with intermediate-dose methotrexate (ID MTX), and intravenous 6-mercaptopurine (IV 6-MP) is superior or inferior to repeated low-dose, oral methotrexate (LDMTX) and IV 6-MP for prevention of relapse in children with ALL in first remission and at lower risk for relapse.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed except for followup purposes. Four new patients entered. Total patients entered: 9.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9006 Status: Ongoing

Title: Alinc 15: Up-Front 6-MP/MTX vs Up-Front Alternating chemotherapy for Acute Lymphocytic Leukemia in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 4  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare, in a randomized trail of children with ALL at higher risk for relapse, the efficacy and toxicity of A: 12 early intensive courses of IV methotrexate (TMX) plus IV 6-mercaptopurine (6-MP) vs B: 12 early intensive courses of alternating intensive chemotherapy combinations (6-MP/MTX), VM-26/Ara-C, Vincristine/prednisone/PEG-L-asparaginase/daunomycin/Ara-C.

Technical Approach: Randomization and therapy will follow the schema outlined in the study protocol.

Progress: One new patient entered on study this year. Study remains open for patient accrual and followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9031 Status: Ongoing

Title: Treatment of Children with High-Stage Medulloblastoma: Cisplatin/VP-16 Pre- vs Post-Irradiation.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Review results:

Objective(s): 1) To compare the 2-year event-free survival (EFS) of children with newly-diagnosed high-risk medulloblastoma who are treated with cisplatin and VP-16 pre-irradiation vs post-irradiation.

2) To define the toxicity and activity of pre- and post-irradiation cisplatin/VP-16 in patients with newly-diagnosed high-risk medulloblastoma.

3) To determine whether achievement of a measurable tumor response (PR and CR) to pre-irradiation cisplatin/VP-16 has prognostic significance for children with high-risk medulloblastoma, compared with failure to achieve a measurable (SD or PD).

Technical Approach: Patients age > 3 years and < 21 years registered within 4 weeks of initial diagnostic surgery or biopsy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. One patient remains in followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9046 Status: Ongoing

Title: Molecular Genetic Study of Wilms' Tumor and Nephrogenic Rests.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To define the patterns of tumor-specific loss of constitutional chromosomal heterozygosity in a large series of Wilms' tumors and associated nephrogenic rests (nephroblastomatosis).  
 2) To correlate these patterns with clinicopathologic findings, to be able, thereby, to propose a new model of pathogenesis for Wilms' tumor.  
 3) To physically localize gene mutations and chromosome abnormalities from specific categories of Wilms' tumors on a long-range physical map of the short arm of chromosome 11.  
 4) To clone genes associated with Wilms' tumor.  
 5) To establish a bank of molecularly and cytogenetically characterized Wilms tumors with matched constitutional tissue.

Technical Approach: Any patient < 16 years of age, with a previously untreated histologically proven Wilms' tumor of any histologic subtype or a mesoblastic nephroma, who has had tumor tissue and blood submitted for study, is eligible. Patients diagnosed prior to the opening of this study are also eligible if both unfixed, frozen pre-treatment tumor and a source of constitutional DNA are available.

Study procedures are outlined in the protocol.

Progress: Study remains open. Three patients entered on study.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9047 Status: Ongoing

Title: Neuroblastoma Biology Protocol.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 5  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To analyze the DNA content of neuroblastoma cells by flow cytometry.

2) To characterize neuroblastoma tumor DNA from POG patients genetically by analysis of N-myc amplification and LOH chromosome 1p.

3) To determine the independent clinical significance of these and other genetic rearrangements compared to more conventional clinical, histologic, and biological variables in predicting either response to treatment or outcome.

4) To develop a reference bank of genetically characterized tumor tissue and DNA that would be available for other current, planned, and future studies of neuroblastoma biology.

Technical Approach: Tumor tissue submitted from diagnostic biopsies or marrow aspirations will be cryopreserved for biologic studies. Eligibility requirements of active neuroblastoma therapeutic studies will require that all patients be concomitantly registered on this study.

Flow cytometry and N-myc studies will be done as outlined in the study protocol.

Progress: Study remains open. A total of five patients entered on study.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9048 Status: Ongoing

Title: Treatment of Children with Localized Malignant Germ Cell Tumors: A Phase II Study.

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine whether > 85% of patients with immature teratomas or Stage I malignant testicular germ cell tumors will have long-term event-free survival when treated with surgery alone, and to estimate a time after which disease recurrence for these patients is very unlikely.  
 2) To determine whether a long-term event-free survival of > 85% can be achieved for children with stage II malignant testicular germ cell tumors and Stage I a II ovarian germ cell tumors who are treated with four courses of chemotherapy with cisplatin, etoposide, and bleomycin.  
 3) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s); extension of disease into local tissues; and extent of lymph node involvement.  
 4) To determine whether initial levels and subsequent changes in tumor markers, specifically alpha-fetoprotein, beta-human chorionic gonadotropin, and LDH, correlate with initial response, ultimate outcome, and disease recurrence.

Technical Approach: Eligible patients must have primary germ cell tumors of the testes or ovaries, which are histologically verified to be yolk-sac tumor, embryonal carcinoma, choriocarcinoma, immature teratoma, or teratoma with malignant elements. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No patients enrolled to date.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9049 Status: Ongoing

Title: Study of High-Risk Malignant Germ Cell Tumors in Children.

Start date: 31 May 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting Period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To compare the efficacy with respect to survival and event-free survival of two chemotherapeutic regimens high-dose cisplatin, etoposide, and bleomycin or standard-dose cisplatin, etoposide, and bleomycin in the treatment of children with high-risk malignant germ cell tumors.  
 2) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s), sites of metastasis, and extent of lymph node involvement.  
 3) To determine whether initial levels and subsequent changes in tumor markers correlate with initial response, ultimate outcome, and the risk of disease progression.

Technical Approach: Patients age < 21 years with histologically verified yolk-sac tumor, embryonal carcinoma, choriocarcinoma, dysgerminoma (seminoma), or teratoma with mixed malignant elements are eligible. Chemotherapy must begin within 2 working days of randomization and within 21 days of the most recent diagnostic surgical procedure.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No patients have been entered on this study.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9061 Status: Completed

Title: The Treatment of Isolated Central Nervous System Leukemia.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the efficacy and toxicity of intensified systemic treatment with delayed craniospinal irradiation for children with acute lymphoblastic leukemia and isolated central nervous system disease.

2) To describe the pharmacokinetics and cytotoxic effect within the cerebrospinal fluid (CSF) of intravenous 6-mercaptopurine (6-MP) given as a single agent in an "up-front" window and to determine the level at which 100% of the blasts are cleared from the CSF.

3) To measure parameters of CNS tissue injury and associate these with the effects of CNS leukemia and treatments.

Technical Approach: Patients with a diagnosis of ALL in first bone marrow remission with isolated, initial CNS relapse are eligible. Patients must be > 1 year of age at time of CNS relapse and must not have had prior brain irradiation.

Therapy will follow the schema outlined in the study protocol.

Progress: Study is completed. No patients have been entered into this study.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9079 Status: Ongoing

Title: Pilot Study, High-Dose Melphalan and Cyclophosphamide with ABM Rescue for Recurrent/Progressive Malignant Brain Tumors

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the acute and delayed toxicities of melphalan and cyclophosphamide followed by ABM rescue in patients with recurrent/progressive brain tumors. 2) To establish the dose level of cyclophosphamide that results in maximum tolerated non-hematologic toxicity, when combined with melphalan. 3) To determine duration of maximum toxicity and time to recovery. 4) To estimate response to therapy, and time to tumor progression.

Technical Approach: Bone marrow harvesting will be carried out as outlined in the study protocol.

Progress: Study closed to new patient enrollment. Two additional patients entered for a total of three. Three patients in followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9107 Status: Completed

Title: Infant Leukemia Protocol.

Start date: 18 Mar 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the toxicity associated with one year of intensive post-induction chemotherapy consisting of rotating courses of high-dose Ara-C/DNR, IV 6-MP/MTX, VP-16/Ara-C, vincristine/prednisone/-cytoxan/Ara-C given to patients < 12 months of age with acute lymphatic leukemia in remission.

2) To determine the incidence, severity, and duration of neutropenia, thrombocytopenia, and anemia associated with each of the above courses.

3) To determine other systemic toxicities (infections, nutritional, etc.) associated with this intensive one-year post-induction chemotherapy.

4) To determine the feasibility of using this regimen in a groupwide phase III protocol for patients < 12 months of age with acute lymphatic leukemia.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed. No patients enrolled to date.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9130 Status: Ongoing

Title: Treatment of Newly-Diagnosed Low Grade Astrocytomas, A Phase III Study

Start date: 27 Jan 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the beneficial effects of irradiation in newly diagnosed low-grade astrocytomas of the brain in childhood. 2) To define the role of surgical resection in newly diagnosed low-grade astrocytomas of the brain in childhood. 3) To determine if adjuvant radiation therapy improves progression-free survival following incomplete surgical resection in children 5-21 years old with newly diagnosed low-grade astrocytomas of the brain. To document the natural history of newly diagnosed low-grade astrocytomas of the brain in patients receiving radical surgical resection as the sole treatment modality. 5) To determine and compare the late effects and neuropsychological sequelae of the various treatments in a large group of children with slow growing brain tumors likely to have long-term progression-free survival or cure.

Technical Approach: All eligible patient will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient enrollment. One patient entered and on followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9132 Status: Completed

Title: Hyperfractionated Irradiation for Posterior Fossa Ependymoma, A Phase II/III Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the feasibility of using hyperfractionated irradiation to the posterior fossa and upper cervical canal to treat newly-diagnosed patients with posterior fossa ependymoma, and to determine the toxicity of this treatment. 2) To evaluate the response of children with incompletely-resected posterior fossa ependymoma to hyperfractionated irradiation. 3) To estimate the disease control interval and pattern of failure of children with posterior fossa ependymoma following treatment with surgery and hyperfractionated irradiation.

Technical Approach: All eligible patients will receive therapy as outlined in the study protocol.

Progress: Study completed. There are no patients on followup.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9136 Status: Ongoing

Title: Phase I/II Dose Escalating Trail of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood.

Start date: 19 Aug 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine the feasibility of using limited volume hyperfractionated radiation therapy to treat children with localized supratentorial malignant gliomas (Group A).  
 2) To determine the feasibility of using hyperfractionated craniospinal irradiation to treat children with poorly-differentiated supratentorial embryonal tumors (PFETs) or supratentorial malignant gliomas associated with neuraxis dissemination (Group B).

Additional objectives as outlined in the study protocol.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. 0 patients entered into study.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9139 Status: Completed

Title: A Dose-Escalating Study of Cisplatin Used Concomitantly with Hyperfractionated Irradiation in the Treatment of Children with Newly Diagnosed Brain Stem Gliomas.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Review results:

Objective(s): 1) To determine the acute and subacute toxicities associated with the administration of cisplatin by continuous infusion, to be used as a radio-sensitizer given simultaneously with a previously tested hyperfractionated irradiation regimen in children with newly-diagnosed brain stem glioma (BSG).

2) To establish the dose level of infusional cisplatin that results in maximum tolerated toxicity when combined with hyperfractionated radiotherapy to the brain stem.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study completed. No patients on followup.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9140 Status: Ongoing

Title: Therapy for Recurrent or Refractory Neuroblastoma.

Start date: 25 Feb 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 2

Periodic review date: Review results:

Objective(s): 1) To determine the response rate and toxicity of three different regimens used to treat patients with resistant or recurrent neuroblastoma: a) Treatment 1 - High-dose cisplatin (HDP) with sodium thiosulfate (STS) plus high-dose VP-16 (HDVP); b) Treatment 2 - high-dose cisplatin (HD-CBDCA) with VP-16 (VP); and c) Treatment 3 - ifosfamide (IFOS) and MESNA with carboplatin (CBDCA).

2) To evaluate the efficacy of 13-cis retinoic acid (RA) in prolonging time to progression of disease for patients with resistant or recurrent neuroblastoma who achieve a response following induction chemotherapy.

3) To measure plasma levels of RA attained during therapy and to determine the correlation of these levels with response to treatment and clinical toxicity.

4) To measure retinoic acid nuclear receptors (RARs) in tumor tissue and to determine their significance in predicting response to therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No new patients.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9151 Status: Ongoing

Title: Intergroup Rhabdomyosarcoma Study-IV for Stage II & III Diseases

Start date: 17 Aug 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the progression-free survival rates of patients receiving vincristine-actinomycin-D-cyclophosphamide (VAC) vs. patients receiving vincristine-actinomycin-D-ifosfamide (VAI) vs. those receiving vincristine-ifosfamide-etoposide (VIE) for treatment of rhabdomyosarcoma and undifferentiated sarcoma.

Technical Approach: All eligible patient will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9190 Status: Ongoing

Title: Intensive Chemotherapy for Stage III Diffuse Undifferentiated Non-Hodgkin's Lymphoma (Burkitt's and Non-Burkitt's

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the toxicity of high-dose Ara-C infusion following high-dose methotrexate, in combination with vincristine and fractionated cyclophosphamide. 2) To correlate Ara-C levels in serum and CSF with toxicity observed.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9193 Status: Ongoing

Title: Autologous Bone Marrow Transplantation for Recurrent/Refractory Non-Hodgkin's Lymphoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): 1) To determine the therapeutic feasibility and acute toxicity of treatment in patients with recurrent non-Hodgkin's lymphoma receiving high-dose chemotherapy or chemoradiotherapy and rescued with autologous bone marrow transplantation (ABMT). 2) To estimate the survival of patients with recurrent HBL using chemotherapy or chemoradiotherapy followed by ABMT.

Technical Approach: All eligible patients will receive treatment as outlined in the study protocol.

Progress: Study closed to new patient accrual. One patient entered on study. Open for followup purposes only.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9222 Status: Ongoing

Title: Mitoxantrone, Etoposide and Cyclosporine (MEC) Therapy in Pediatric Patients with Acute Myeloid Leukemia

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: Closed to new pts

Objective(s): 1) To determine the remission rate and toxicity to mitoxantrone, etoposide and cyclosporine. 2) To measure mdrl and topoisoemrase II messenger RNA levels by PCR in myeloid leukemia cells prior to starting therapy. 3) To detect mdrl p-glycoprotein and function in leukemic blasts.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for followup of patients only.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9225 Status: Ongoing

Title: 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low-dose radiotherapy). 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low dose-radiotherapy. 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Technical Approach: Patients less than 21 years of age with histologic proof of Hodgkin's disease will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 95      Protocol Number: POG 9226      Status: Ongoing

Title: Treatment of Stage I, IIA and IIIA, Hodgkins Disease with ABE and Low-Dose Irradiation

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) To study the activity of four cycles of Adriamycin, bleomycin, vincristine and etoposide (ABVE) followed by 2550 Cgy irradiation in clinically or pathologically staged I, II and IIIA, Hodgkin's disease. 2) To establish the response (CR & PR) rate following four cycles of ABVE. 3) To determine the incidence of major therapy related immediate and late effects of the above regimen. 4) To reduce the morbidity associated with therapy without decreasing the efficacy of treatment in Early Stage Hodgkin's Disease. 5) To correlate the results of clinical, imaging, laboratory staging with surgical/pathological staging where performed.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient accrual.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9243 Status: Ongoing

Title: Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, and DS (<365 Days at Diagnosis)

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine and compare the acute and long-term toxicities experienced by patients treated on Arm A with patients who previously received the same treatment without G-CSF on POG #8743. 2) To determine the acute and long-term toxicities associated with treatment on Arm B. 3) To assess the relationship of specific biological features of neuroblastoma, as determined on POG #9047, to clinical presentation, response to therapy, and survival. 4) To use G-CSF to ameliorate myelosuppression and its associated morbidity, and thus potentially to reduce the cost of therapy. 5) To determine if G-CSF can improve the dose interval, and therefore the dose intensity on Arm A, compared to that achieved on POG #8743. 6) To determine the short and long-term toxicities associated with the use of G-CSF in infants.

Technical Approach: All eligible patients will be enrolled for therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment. One patient has been entered on study.



# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9259 Status: Ongoing

Title: Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresected Osteosarcoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

ber of subjects enrolled during reporting period: \_\_\_\_\_ Num  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the response rate to carboplatin in patients presenting with newly-diagnosed metastatic or unresectable osteosarcoma prior to treatment with other chemotherapeutic agents.

Technical Approach: All eligible patients with metastatic disease or unresectable osteosarcoma will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9264 Status: Ongoing

Title: Chemotherapy Regimen for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the complete remission rate for initial induction failures in childhood ALL based on an induction regimen of methotrexate and 6-mercaptopurine. 2) To estimate the one-year disease-free survival for initial induction failures in childhood ALL, based on a new regimen. 3) To try and better characterize this unique subpopulation of patients with primary drug resistance using CDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

Technical Approach: All patients less than 21 years of age at time of initial diagnosis with acute lymphoblastic (T or B cell lineage) leukemia will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9280 Status: Ongoing

Title: Neuroblastoma Epidemiology Protocol

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the relationship between environmental exposures and the occurrence of neuroblastoma. 2) To evaluate the relative importance of risk factors for neuroblastoma reported in previous epidemiologic studies. 3) To collect information on additional potential risk factors that can be used to develop new hypotheses such as parental smoking, parental radiation exposure, family history of cancer, gestational and delivery history. 4) To determine the relationship between environmental factors and host factors by evaluating subgroups of cases defined by biologic factors and clinical characteristics.

Technical Approach: Study will include majority of cases newly diagnosed in the US and Canada each year who are registered by the two clinical trials groups. Controls will be identified by using random digit dialing procedure. Case and control parents will be interviewed by telephone. Clinical and biologic data will be collected as part of the cooperative group biological and therapeutic protocols will be used to define subgroups of patients.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9310 Status: Ongoing

Title: SIMAL #7: Escalating Rotational Drug Therapy After First Marrow Relapse of Non-T, Non-B ALL - A Pediatric Oncology Groupwide Pilot Study.

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) Increase the event-free survival (EFS) of children with acute lymphoblastic leukemia (ALL) following first marrow relapse or first relapse in an extramedullary site other than CNS. A rotating, escalating, weekly parenteral drug regimen will be used for continuation therapy. A single army pilot study is planned. 2) To determine the feasibility of giving G-CSF to patients with recurrent ALL and whether administration of G-CSF in continuation therapy will allow for escalation of myelotoxic agents known to be active in ALL. 3) To compare two induction delivery schedules for PEG-L asparaginase in terms of PEG-L asparaginase pharmacokinetics, and surrogate measures such as asparaginase level, and change in asparaginase antibody levels between day 0 and day 28.

Technical Approach: All eligible patients will receive treatment as outlined in the study protocol.

Progress: One patient remains on followup. Study remains open for patient accrual.

# Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9340/41/42 Status: Ongoing

Title: Treatment of Patients > 365 Days at Diagnosis with Stage 4 and N-MYC Amplified Stage 2B/3 Neuroblastoma

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) To evaluate the response rate to and toxicity of Phase II single-agent chemotherapy (either taxol, or topotecan) given prior to Phase III therapy to two successive subsets of untreated patients (pts) > 365 days of age with INSS Stage 4 neuroblastoma (NB). 2) To measure response rates and toxicity, event-free survival (EFS), survival, and patterns of failure, of pts treated with 6 courses of induction chemotherapy; high dose platinum/VP-16 (HDP/VP), cyclophosphamide/Adriamycin/Vincristine (CAV), ifosfamide/VP (IFOS/VP), CBDCA/VP, HDP/VP, and CAV plus G-CSF, followed by local radiotherapy and autologous bone marrow transplantation (ABMT), (POG #9342). 3) To measure response rates, toxicity, EFS, survival, and patterns of failure of pts whose families decline ABMT, and therefore receive an additional 5 courses of therapy (IFOS/VP, CAV, HDP/VP, CAV, CBDCA/VP) plus G-CSF followed by local radiotherapy to the tumor bed. 4) To further evaluate the toxicity of autologous bone marrow transplantation (ABMT) using cyclophosphamide/VP/CBDCA ablation plus local radiotherapy (POG #9342). 5) To measure EFS, survival, and patterns of failure of pts who achieve a complete response or partial response or mixed response (see Sec. 7.0) at the end of induction chemotherapy prior to ABMT. 6) To further evaluate the biologic parameters of neuroblastoma as required for POG 9047, and to measure MDR-1 protein (P-glycoprotein) levels, which will be obtained at diagnosis and in marrow purgates and/or available tumor tissue during therapy, with correlation to clinical presentation at diagnosis, clinical course, response to therapy, and survival.

POG 9340/41/42 (continued)

Technical Approach: All eligible patients will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient accrual.

## Detail Summary Sheet

Date: 15 Dec 95 Protocol Number: POG 9340/41/42 Status: Ongoing

Title: Treatment of Patients > 365 Days at Diagnosis with Stage 4 and N-MYC Amplified Stage 2B/3 Neuroblastoma

Start date:	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1) To evaluate the response rate to and toxicity of Phase II single-agent chemotherapy (either taxol, or topotecan) given prior to Phase III therapy to two successive subsets of untreated patients (pts) > 365 days of age with INSS Stage 4 neuroblastoma (NB). 2) To measure response rates and toxicity, event-free survival (EFS), survival, and patterns of failure, of pts treated with 6 courses of induction chemotherapy; high dose platinum/VP-16 (HDP/VP), cyclophosphamide/Adriamycin/Vincristine (CAV), ifosfamide/VP (IFOS/VP), CBDCA/VP, HDP/VP, and CAV plus G-CSF, followed by local radiotherapy and autologous bone marrow transplantation (ABMT), (POG #9342). 3) To measure response rates, toxicity, EFS, survival, and patterns of failure of pts whose families decline ABMT, and therefore receive an additional 5 courses of therapy (IFOS/VP, CAV, HDP/VP, CAV, CBDCA/VP) plus G-CSF followed by local radiotherapy to the tumor bed. 4) To further evaluate the toxicity of autologous bone marrow transplantation (ABMT) using cyclophosphamide/VP/CBDCA ablation plus local radiotherapy (POG #9342). 5) To measure EFS, survival, and patterns of failure of pts who achieve a complete response or partial response or mixed response (see Sec. 7.0) at the end of induction chemotherapy prior to ABMT. 6) To further evaluate the biologic parameters of neuroblastoma as required for POG 9047, and to measure MDR-1 protein (P-glycoprotein) levels, which will be obtained at diagnosis and in marrow purgates and/or available tumor tissue during therapy, with correlation to clinical presentation at diagnosis, clinical course, response to therapy, and survival.

## Detail Summary Sheet

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Date: 1 Dec 95      Protocol Number: GOG 26      Status: Ongoing

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Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start date: Reopened Feb 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s): Reginald Moore, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

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Number of subjects enrolled during reporting period: 1 (26 LL)

Total number of subjects enrolled to date: 1

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

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Objective(s): This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol.

Progress: This study was terminated 23 May 94. However, because there is still one patient on followup, this study remains ongoing for patient followup but is closed to new patient entry.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 26-A Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To evaluate a succession of new agents (cytotoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 26C

Status: Ongoing

Title: A Phase II Trial of Cis-Platinum (NSC #119875) in Patients with Advanced Pelvic Malignancies

Start date:

Estimated completion date:

Principal Investigator:  
LTC Kevin Hall, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Obstetrics-Gynecology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the level of effectiveness of one of the new drug agents, cis-platinum for which the true effectiveness in cancer of the female organs has not yet been determined.

Technical Approach: As outlined in the protocol.

Progress: This study was reported as completed by error in 1993. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 26-II Status: Ongoing

Title: A Phase II Trial of 5-Fluorouracil and Leucovorin in Advanced, Metastatic, or Recurrent Pelvic Malignancies

Start date: 8 Aug 95	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to compare the effectiveness of different methods of treating cancer of the female genital organs. A combination of drugs are being evaluated as to their possible effectiveness in the treatment of carcinoma of the female genital organs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. There is no available data.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 26KK

Status: Ongoing

Title: A Phase II Trial of Merbarone in patients with Advanced and Recurrent Endometrial, Cervical and Epithelial Ovarian Carcinoma

Start date:

Estimated completion date:

Principal Investigator:  
LTC Kevin Hall, MC

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Department of Obstetrics-Gynecology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to evaluate the effectiveness of this single agent in the treatment of cancer of the female genital organs.

Technical Approach: As outlined in the protocol.

Progress: Due to administrative error, this study was reported as closing in 1993. It should have been listed as ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 26-LL Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvic Malignancies

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To evaluate a succession of new agents (cytotoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 81F Status: Ongoing

Title: A Phase II Trial of Tamoxifen Citrate in Patients with Advanced or Recurrent Carcinoma Responsive to Progestins

Start date: 16 Dec 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine whether patients with endometrial carcinoma who have responded to medroxyprogesterone acetate and then progressed will respond to a second hormonal manipulation in the form of tamoxifen citrate. 2) To evaluate the level of efficacy (response rate) of tamoxifen in patients with advanced or recurrent endometrial carcinoma not previously exposed to hormonal therapy for their malignancy.

Technical Approach: Patients will receive tamoxifen 20 mg p.o. BID and treatment will be continued until there is evidence of disease progression. Patients will be seen at least once monthly for 3 months after initiation of therapy. If disease process is at least stable, subsequent visits may be less frequent but must occur at least every 3 months.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 87 Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in the Treatment of Recurrent or Advanced Uterine Sarcomas.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To identify new agents and agent combinations for the treatment of patients with recurrent or advanced metastatic sarcoma.

Technical Approach: Therapy for each phase II drug study will follow the schedule outlined in the study protocol. In addition to the master protocol, the study has been approved for 87F - Doxorubicin and Ifosfamide with Mesna.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 87-D Status: Ongoing

Title: A Phase II Trial of VP-16 in Patients with Advanced or Recurrent Uterine Sarcomas

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To indicate the need for identification of new agents and combinations for treating this malignancy. To allow the best possible chance for a new cytotoxic agent to demonstrate activity, this study constitutes a Phase II design in a population of patients who have had no prior drug therapy.

Technical Approach: The study design involves treating an average sample size of 30 evaluable patients per drug studied for each of the following cell type categories: mixed mesodermal tumor, leiomyosarcoma, and other sarcomas. Sections relating to specific agents will be sequentially incorporated into this protocol as each agent is studied.

Progress: This protocol remains open for patient entry. No patients have as yet been enrolled.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 87-G Status: Ongoing

Title: A Phase II Trial of Paclitaxel (Taxol) in Patients with Advanced or Recurrent Uterine Sarcomas

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Paclitaxel will be administered as a 3-hour continuous infusion at an initial dose of 175 mg/m<sup>2</sup>/3 hours every 3 weeks. The starting dose should be reduced to 135 mg/m<sup>2</sup>/3 hours for patients who have had prior pelvic radiation therapy.

Technical Approach: As outlined in the study.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 87-H Status: Ongoing

Title: A Phase II Trial of Topotecan (NSC #609699) in Patients with Advanced, Persistent or Recurrent Uterine Sarcomas

Start date: 8 Aug 95	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the effectiveness of topotecan in treating advanced or recurrent sarcoma of the uterus.

Technical Approach: Therapy will follow the schedule outlined in the study protocol.

Progress: This is a new study. There is no available data.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: GOG 90      Status: Ongoing

Title: Evaluation of Cisplatin, Etoposide and Bleomycin (BEP) Induction  
Followed by Vincristine, Dactinomycin, and Cyclophosphamide (VAC)  
Consolidation in Advanced Ovarian Germ Cell Cancer

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s):

Technical Approach: As outlined in the protocol.

Progress: This study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: GOG 92                      Status: Ongoing

Title: Treatment of Selected Patients with Stage IB Carcinoma of the Cervix After Radical Hysterectomy and Pelvic Lymphadenectomy: Pelvic Radiation Therapy vs No Further Therapy

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the value of adjunctive pelvic radiation in the treatment of Stage IB carcinoma of the cervix, but with selected high-risk factors. 2) To determine the recurrence-free interval, survival and patterns of failure in these patients. 3) To determine the morbidity of adjunctive pelvic radiation following radical hysterectomy.

Technical Approach: As outlined in the protocol.

Progress: This study was reported as being completed in 1993. It should have been reported as ongoing for patient followup but closed to new patient entries.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 93 Status: Ongoing

Title: Evaluation of Intraperitoneal Chromic Phosphate Suspension Therapy Following Negative Second Look Laparotomy for Epithelial Ovarian Carcinoma (Stage III).

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the role of intraperitoneal chromic phosphate suspension (intraperitoneal <sup>32</sup>P) therapy in patients with Stage III epithelial ovarian carcinoma who have no detectable evidence of disease at the second-look laparotomy.

Technical Approach: Patients with primary histologically confirmed epithelial carcinoma of the ovary in clinical remission are eligible. Patients with no persistent or recurrent cancer as assessed by surgical, cytologic and histologic findings at the second-look laparotomy likewise are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 95 Status: Ongoing

Title: Randomized Clinical Trial for the Treatment of Women with Selected Ic and II(A,B,C) and Selected Stage IAI & IAI and BII Ovarian Cancer (Phase III).

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To compare the progression free interval and overall survival of the two treatment regimens.

2) To determine the patterns of relapse for each form of therapy.

3) To define the relative toxicities of the two treatment approaches.

Technical Approach: Patients meeting the eligibility criteria will be treated in accordance with the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 99 Status: Ongoing

Title: A Phase III Randomized Study of Surgery vs. Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: Review results:

Objective(s): 1) To determine if patients with intermediate risk endometrial adenocarcinoma (as defined below), who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy.

2) To evaluate how the addition of pelvic radiotherapy will alter the site and rate of cancer recurrence in these intermediate risk patients.

Technical Approach: Patients with primary histologically confirmed Grades 1, 2, and 3 endometrial adenocarcinoma are eligible. Patients must have had a total abdominal hysterectomy, bilateral salpingo-oophorectomy, selective and para-aortic node sampling, pelvic washings and are found to be surgical Stage I and occult Stage II. Myometrial invasion must be present.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment. Four patients have entered study thus far.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 100 Status: Ongoing

Title: Monoclonal Antibody Against Free Beta HCG to Predict Development of Persistent Gestational Trophoblastic Disease (PGTD) in Patients with Hydatidiform Mole

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 25 Jul 94 Review results:

Objective(s): To measure the serum concentration of free beta HCG and total beta HCG in patients with molar pregnancies in order to determine whether the ratio of free beta HCG to total beta HCG may be of value in predicting which molar pregnancies will undergo spontaneous remission and which will subsequently develop into persistent gestational trophoblastic disease.

Technical Approach: Serum samples will be obtained weekly until a negative assay is attained or until a plateau or rise in titer is observed. A beta HCS will be performed by each institution for their clinical management of the patient. A 5cc aliquot of this serum will be collected and frozen. When the patient is in complete remission or PGTD is encountered, the samples will be sent to the Southern Regional Trophoblastic Disease Center for free beta HCG assay.

Progress: Study remains ongoing for patient followup and data accrual.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 102 Status: Ongoing

Title: Master Protocol for Phase II Intraperitoneal Drug Studies in Treatment of Minimal Residual Ovarian Malignancies Documented at Second-Look Surgery.

Start date: 15 Apr 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine the activity of various drugs or BRMs alone or in combination when used by the intraperitoneal route in patients who have persistent minimal residual disease epithelial ovarian malignancies after standard therapy.

2) To evaluate further the toxicity, systemic and local, of drugs and BRMs or combinations used in this study.

Technical Approach: Therapy for the following arms will follow the schema outlined in the study protocol: 102F - Alpha Recombinant Interferon (AIFN); 102G - Cisplatin and Thiotepa; and 102H - Interleukin-2; and 102N - Intraperitoneal Recombinant Alpha-2-Interferon.

Progress: No patients have been entered on this study.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: GOG 104                      Status: Ongoing

Title: Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide vs  
Intravenous Cis-Platinum/Intravenous Cyclophosphamide in Patients with Non-  
Measurable (Optimal) Disease Stage III Ovarian Cancer, Phase III

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to compare the benefits, effectiveness and safety of two different ways of giving drugs (chemotherapy) for the treatment of patients with ovarian cancer. The drugs used in this study are commonly given intravenously (by injection into a vein), one of the drugs will be given either intravenous or intraperitoneally (placed directly into the space around the stomach and intestines - abdomen).

Technical Approach: As outlined in the protocol.

Progress: This study was closed in 1993 due to error in reporting protocol status. It should have been listed as ongoing to patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 107

Status: Ongoing

Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Patients with Primary Stage III and IV, Recurrent Endometrial Adenocarcinoma (Phase III)

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, the duration of progression-free interval, and the length of survival as compared to doxorubicin alone.

Technical Approach: All patients with histologically documented primary Stage III or Stage IV, or recurrent endometrial adenocarcinoma, adenocanthoma, or adenosquamous carcinoma whose potential for cure by radiation therapy or surgery alone or in combination is very poor will be eligible. Measurements by sonography and/or CT scans are acceptable if the mass is sharply defined. Therapy will follow the schema outlined in the study protocol.

Progress: Due to reporting error study was closed in 1993. Study should have been reported as ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 108 Status: Ongoing

Title: Ifosfamide (NSC#109724) and the Uroprotector Mesna (NSC#113891) With or Without Cisplatin (NSC#119875) in Patients with Advanced, Persistent or Recurrent Mixed Mesodermal Tumors of the Uterus (Phase III)

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To confirm reported high response rates of advanced or recurrent mixed mesodermal tumors of the uterus to ifosfamide/Mesna. 2) To determine whether the addition of Cisplatin to Ifosfamide/Mesna improves response rates or survival in patients with these tumors. 3) To determine the toxicity of Ifosfamide/Mesna with Cisplatin in patients with these tumors.

Technical Approach: Patient will be hydrated prior to institution of therapy with 1000 cc of normal or one-half normal saline at a rate to maintain urine output at greater than 100 cc/hour. Patients randomized to Ifosfamide without platinum therapy will be instituted with bolus of Mesna 120 mgm/m<sup>2</sup> 15 minutes prior to the Ifosfamide. Ifosfamide will be administered. After completing the Ifosfamide, the Mesna will be administered by continuous infusion over five days uninterrupted except on subsequent days when Ifosfamide is administered. For patients receiving Cisplatin, platinum administration will precede the Ifosfamide therapy and should be reconstituted to concentration of approximately 1 mgm/cc and infused at a rate of 1 mgm/min.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 109 Status: Ongoing

Title: A Randomized Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy, Versus Radiation Therapy Alone in Selected Patients with Stages I-A2, I-B, and II-A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine whether the combination of 5-fluorouracil (5-FU) and cisplatin used as an adjunct to radiation therapy will improve survival rate or progression-free survival and decrease extra pelvic failure compared to radiation therapy alone in patients with positive pelvic lymph nodes, positive parametrial involvement or positive surgical margins following radical hysterectomy and lymph node dissection for Stages I-A2, I-B and II-A carcinoma of the cervix. 2) To determine the increase in toxicities due to 5-FU and cisplatin as an adjunct to radiation therapy versus radiation therapy alone.

Technical Approach: All eligible patients will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 110 Status: Ongoing

Title: A Randomized Comparison of Cisplatin Versus Cisplatin Plus Dibromodulcitol (NSC#104800) Versus Cisplatin Plus Ifosfamide and Mesna in Advanced Carcinoma of the Cervix

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Review results:

Objective(s): 1) To determine if mitolactol plus cisplatin or ifosfamide plus cisplatin improves response rate, response duration, progression-free interval and/or survival in advanced squamous cervical cancer compared to cisplatin alone. 2) To compare the toxicity of these three regimens in advanced cervical cancer.

Technical Approach: Patients will be stratified according to whether or not they have had prior cisplatin as a radiation sensitizer and by performance status. Under Regimen I, cisplatin 50 mg/m<sup>2</sup> with hydration will be repeated every three weeks and treatment will continue until disease progresses or until toxicity prohibits further therapy or for a maximum of six courses. Regimen II will include cisplatin plus dibromodulcitol (mitolactol), DBD) and treatment will continue until toxicity prohibits further or for a maximum of six courses. Regimen III will include cisplatin plus ifosfamide (plus mesna). Cisplatin 50 mg/m<sup>2</sup> with hydration per GOG guidelines plus ifosfamide 5.0 grams/m<sup>2</sup> in 1 liter of dextrose and saline over 24 hrs plus mesna 6 grams/m<sup>2</sup> will be given concurrently with ifosfamide and for 12 hrs after every 3 weeks. Mesna should be given as 2 gm/m<sup>2</sup> in 1 liter of dextrose/saline or normal saline every 12 hours as a separate infusion which can be "piggy-backed" into the intravenous line for the ifosfamide.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: GOG 111      Status: Ongoing

Title: A Phase III Randomized Study of Cyclophosphamide and Cisplatin vs Taxol and Cisplatin in Patients with Suboptimal Stage III and IV Epithelial Ovarian Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine response rate, response duration and survival in suboptimal Stage III and Stage IV ovarian cancer treated with two different platinum-based combination chemotherapy regimens. 2) To evaluate the relative activity and toxicities of a new combination, cisplatin/taxol, as compared to the standard regimen, cisplatin/cyclophosphamide.

Technical Approach: Patients with established ovarian epithelial cancer, suboptimal Stage III and Stage IV will be eligible. All patients must have optimal surgery for ovarian cancer, with at least exploratory laparotomy and appropriate tissue submitted for histologic examination.

Progress: Due to error in reporting this study was reported as closed in 1993. Study remains ongoing for patient accrual and patient followup.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 112 Status: Ongoing

Title: A Randomized Comparison of Chemoprophylaxis Using Methotrexate Versus Routine Surveillance in the Management of the High Risk Molar Pregnancy.

Start date: 15 Apr 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 5  
 Periodic review date: Review results:

Objective(s): 1) To determine the incidence of post molar trophoblastic disease after evacuation of the high risk molar pregnancy in those patients receiving chemoprophylaxis versus those randomized to usual post evacuation surveillance. 2) To evaluate the toxicity associated with chemoprophylaxis. 3) To develop a clinical pathologic scoring system for risk of postmolar trophoblastic disease which highly correlates with the serum free beta HCG assay.

Technical Approach: As outlined in the study protocol.

Progress: Data results of the previously enrolled patients are currently not available. Study remains ongoing for patient followup.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 114 Status: Ongoing

Title: A Phase II Randomized Study of Intravenous Cisplatin and Cyclophosphamide Versus Intravenous Cisplatin and Taxol Versus High Dose Intravenous Carboplatin Followed by Intravenous Taxol and Intraperitoneal Cisplatin in Patients with Optimal Stage III Epithelial Ovarian Carcinoma

Start date: Jun 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To compare recurrence-free interval, complete pathologic response, and survival between the standard regimen: intravenous cisplatin/cyclophosphamide and the two experimental regimens: Intravenous cisplatin/taxol and intravenous carboplatin followed by intravenous taxol and intraperitoneal cisplatin in patients with optimal (< 1 cm residual) stage III epithelial ovarian carcinoma. 2) To compare the toxicities and complications of the three treatment regimens. 3) To correlate serial serum CA-125 levels with negative second look and recurrence-free interval.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: GOG 115      Status: Ongoing

Title: Bleomycin, Etoposide and Cisplatin as First Line Therapy of Malignant Tumors of the Ovarian Stroma (Granulosa Cell, Sertoli-Leydig Tumor, and Unclassified Sec Cord Stromal Tumor)

Start date: 20 May 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of bleomycin, etoposide (VP-16), and cisplatin (BEP) chemotherapy in patients with malignant tumors of the ovarian stroma of the ovary as a first-line regimen.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: An error occurred when reporting the status of this protocol. It was reported as complete. It should be ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 116 Status: Ongoing

Title: Evaluation of Adjuvant VP-16 and Carboplatin Therapy in Totally Resected Ovarian Dysgerminoma

Start date: 20 May 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the effect of adjuvant VP-16 and carboplatin chemotherapy in patients with completely resected ovarian dysgerminoma. 2) To evaluate the acute and chronic toxicity of this chemotherapy on gonadal and reproductive function.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study was reported in March 1993 as being closed. It should have been reported as ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 117 Status: Ongoing

Title: Adjuvant Ifosfamide and Mesna with Cisplatin in Patients with Completely Resected Stage I or II Mixed Mesodermal Tumors of the Uterus.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine whether cisplatin and ifosfamide/mesna can determine the recurrence rate in patients with completely resected stage I or II mixed mesodermal tumors of the uterus.

2) To determine whether postoperative chemotherapy is more effective than surgery alone in local (pelvic) control of these tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 118 Status: Ongoing

Title: Evaluation of the Predicted Value of antineoplastic Drug Resistance Determined by in vitro Assay.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To evaluate the correlation between response to chemotherapy and in vitro drug resistance assessed by two laboratory endpoints (cytostatic and cytocidal) in untreated epithelial ovarian carcinoma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 119 Status: Ongoing

Title: A Study of the Use of Provera and Nolvadex for the Treatment of Advanced, Recurrent, or Metastatic Endometrial Cancer.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine the efficacy of tamoxifen citrate plus intermittent administration of Provera<sup>®</sup> (Medroxyprogesterone Acetate) in patients with recurrent or metastatic endometrial carcinoma.

2) To determine the side effects of such treatment in patients with this disease.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 120 Status: Ongoing

Title: A Randomized Comparison of Hydroxyurea Versus Hydroxyurea, 5-FU Infusion and Bolus Cisplatin Versus Weekly Cisplatin as Adjunct to Radiation Therapy in Patients with Stages II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes

Start date: 20 Apr 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine whether hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin is superior as a potentiator of radiation therapy in locally advanced cervical carcinoma. 2) To determine the relative toxicities of hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin given concurrently with radiation therapy.

Technical Approach: Patients with untreated cervical carcinoma Stages II-B, III-A, III-B and IV-A, who have fulfilled the eligibility requirements according to Section 3.0 will receive pelvic radiotherapy as outlined and will be randomized according to regimens outlined in study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 121 Status: Ongoing

Title: A Phase II Trial of High Dose Megestron Acetate (Megace) in Advanced or Recurrent Endometrial Carcinoma

Start date: 21 Oct 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine the response rate and progression-free interval in patients receiving high dose megestrol acetate (Megace) for advanced or recurrent endometrial carcinoma. 2) To determine the toxicity of high dose megestrol acetate in such patients. 3) To determine if estrogen/progesterone receptor status is predictive of response.

Technical Approach: Patients will take orally two tablets at breakfast, two tablets at lunch and one tablet at dinner for a total daily dose of 800 mg. Therapy will continue as outlined in the study protocol.

Progress: Study remains open for data accrual.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 122 Status: Ongoing

Title: Whole Abdominal Radiotherapy Versus Circadian-Timed Combination Doxorubicin-Cisplatin Chemotherapy in Advanced Endometrial Carcinoma

Start date: 19 Nov 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To compare treatment outcomes (survival and progression-free interval) and failure patterns in patients with stages II-IV endometrial carcinoma (< 2 cm residual disease) treated with whole abdominal irradiation versus combination doxorubicin-cisplatin chemotherapy. 2) To determine and compare the incidence and type of acute and late adverse events observed with the two treatment regimens.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 123 Status: Ongoing

Title: A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy in Patients with Bulky Stage IB Carcinoma of the Cervix, Phase III

Start date: 19 Nov 91	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine if weekly cisplatin infusion improves local regional control and survival when added to radiation therapy plus extrafascial hysterectomy. 2) To determine the relative toxicities of these two treatment arms.

Technical Approach: In this study, we plan to compare the addition of weekly cisplatin infusion with current apparent better arm of Protocol #71; radiation therapy plus adjuvant hysterectomy in patients with bulky Stage IB carcinoma of the cervix.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 125 Status: Ongoing

Title: Extended Field Radiation Therapy with Concomitant 5-FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes, Phase II

Start date: 27 Jan 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Review results:

Objective(s): Patients with uterine cervical carcinoma who have biopsy confirmed para-aortic lymph node metastases will receive combination chemotherapy consisting of displatin and 5-FU intravenous infusion concomitantly with pelvic and para-aortic extended field radiation therapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the uterine cervix (squamous, adenosquamous and adenocarcinoma and all clinical stages (except clinical Stage IIIA and IVB), with metastasis to para-aortic lymph nodes proven by cytologic or histologic means will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 126-B Status: Ongoing

Title: Evaluation of Cisplatin & Cyclosporin in Recurrent, Platinum Resistant & Refractory Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the antitumor activity of cisplatin and cyclosporin in patients with recurrent, platinum-resistant or refractory ovarian cancer who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of cisplatin and cyclosporin in this cohort of patients.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open for patient entry. No enrollments have occurred to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 126-C Status: Ongoing

Title: A Phase II Evaluation of Altretamine (Hexamethylmelamine) in Recurrent, Platinum-Resistant and Refractory Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: March 1995 Review results: \_\_\_\_\_

Objective(s): This protocol is to estimate the antitumor activity of altretamine in patients with recurrent, platinum-resistant or refractory ovarian cancer who have failed on higher priority treatment protocols and to determine the nature and degree of toxicity of altretamine in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: GOG 127-F      Status: Ongoing

Title: Evaluation of Topotecan in Persistent or Recurrent Squamous Cell Carcinoma of the Cervix

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the antitumor activity of topotecan in patients with persistent or recurrent squamous cell carcinoma of the cervix who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of topotecan in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: GOG 127-H      Status: Ongoing

Title: Evaluation of Prolonged Oral Etoposide (VP-16) in Persistent or Recurrent Squamous Cell Carcinoma of the Cervix

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is 1) To estimate the antitumor activity of prolonged oral etoposide (VP-16) in patients with persistent or recurrent squamous cell carcinoma of the cervix who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of prolonged oral etoposide (VP-16) in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 128-B Status: Ongoing

Title: Evaluation of Paclitaxel in Persistent of Recurrent Non-Squamous Cell Carcinoma of the Cervix and Vagina

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To estimate the antitumor activity of paclitaxel in patients with persistent or recurrent non-squamous cell carcinoma of the cervix and DES-associated clear cell adenocarcinoma of the vagina and cervix who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of paclitaxel in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 129-B Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in the Treatment of Recurrent or Advanced Endometrial Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To estimate the antitumor activity of oral VP-16 in patients with metastatic or advanced endometrial carcinoma who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of oral VP-16 in this cohort of patients.

Technical Approach: Etoposide (VP-16) will be administered orally at a dosage of 50 mg/m<sup>2</sup>/day, day 1-21 every 4 weeks. Patients will be instructed to return capsule card to insure protocol compliance. Patients who have received prior radiation will be treated at 30 mg/m<sup>2</sup>.

Progress: Study closed to new patient entry June 1994. There is no reportable data at this time.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 129-C Status: Ongoing

Title: Evaluation of Paclitaxel (Taxol) in the Treatment of Recurrent or Persistent Endometrial Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: March 1995 Review results: \_\_\_\_\_

Objective(s): This purpose of this study is to estimate the antitumor activity of paclitaxel (Taxol) in patients with persistent or recurrent endometrial carcinoma who have failed on higher priority treatment protocols and to determine the nature and degree of toxicity of paclitaxel in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 130-B Status: Ongoing

Title: Evaluation of Paclitaxel (Taxol) in the Treatment of Advanced or Recurrent Mixed Mesodermal Tumors of the Uterus

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to estimate the antitumor activity of paclitaxel (Taxol) in patients with persistent or recurrent mixed mesodermal tumors of the uterus who have failed on higher priority treatment protocols and to determine the nature and degree of toxicity of paclitaxel in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 131-B Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Metastatic or Advanced Leiomyosarcoma of the Uterus

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to estimate the antitumor activity of oral VP-16 in patients with metastatic or advanced leiomyosarcoma of the uterus who have failed on higher priority treatment protocols and to determine the nature and degree of toxicity of oral VP-16 in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 132 Status: Ongoing

Title: A Phase III Trial of Taxol at Three Dose Levels and G-CSF at Two Dose Levels in Platinum-Resistant Ovarian Carcinoma

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine the relative efficacy of regimens consisting of taxol versus cisplatin versus a combination of the two drugs in patients with suboptimally debulked stage III & IV epithelial ovarian cancer. 2) To determine which of the three regimens contribute most favorably to progression-free interval and survival. 3) To compare the incidence of audiologic sequelae and other toxicities arising from any of the three regimens.

Technical Approach: Once patient eligibility is determined, therapy will continue as outlined in study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 134 Status: Ongoing

Title: Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To determine if the dose of taxol affects response rate, progression-free interval or survival in patients with platinum-resistant ovarian cancer. 2) To compare the toxicities of the three regimens. 3) To compare the efficacy and toxicity of two dose levels of G-CSF (5 ug/kg/day versus 10 ug/kg/day) in patients who receive the highest taxol dose (250 mg/m<sup>2</sup>). 4) To determine the relationship between peak taxol plasma concentration and toxicity/response.

Technical Approach: Patients with platinum-resistant ovarian epithelial cancer stage III and stage IV will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 135 Status: Ongoing

Title: Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)

Start date: 18 May 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1) To evaluate the correlation between the ATP-cell viability assay (ATP-CVA) and patient response to chemotherapy in untreated primary epithelial ovarian carcinoma. 2) To correlate laboratory results with the achievement of Pathologic CR at time of 2nd look surgery. 3) To correlate laboratory results with progression-free survival. 4) To correlate single agent and combined agent in vitro studies with clinical outcome.

Technical Approach: Patients with primary ovarian epithelial carcinoma who are eligible will receive therapy as outlined in study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 136 Status: Ongoing

Title: Acquisition of Human Ovarian and Other Tissue Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

Start date: 22 Jun 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): 1) To accomplish the collection of human ovarian tissue specimens and serum within GOG participating institutions. 2) To provide a repository for long-term storage of ovarian tumor, tissue and serum. 3) To make available through the Cooperative Human Tissue Network (CHTN), tumor tissue and serum for proposed projects conducted by GOG Investigators (internal bank) and by researchers nationally (external bank).

Technical Approach: All eligible patients who have had ovarian tumor tissue removed including all epithelial tumors, germ cell, sex cord stromal and other primary ovarian malignancies will receive therapy as outlined in the study protocol.

Progress: Study remains open for data accrual.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 137 Status: Ongoing

Title: A Randomized Trial of Estrogen Replacement Therapy Versus no Estrogen Replacement in Women with Stage I or II Endometrial Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of estrogen replacement therapy on recurrence-free and overall survival in women with a history of stage I or II endometrial adenocarcinoma.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open to patient entry.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 138 Status: Ongoing

Title: A Phase II Trial of Cisplatin and Cyclophosphamide in the Treatment of Extraovarian Peritoneal Serous Papillary Carcinoma

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the response rate, and response duration in patients with extraovarian peritoneal serous papillary carcinoma treated with a combination of cisplatin and cyclophosphamide.

Technical Approach: Once patient has been determined eligible, treatment will initiated as outlined in the study protocol.

Progress: Study remains open for data accrual.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 139

Status: Ongoing

Title: A Randomized Study of Doxorubicin Plus Cisplatin Versus Circadian-timed Doxorubicin Plus Cisplatin in Patients with Primary Stage III & IV, Recurrent Endometrial Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if circadian-timed doxorubicin-cisplatin chemotherapy offers significant improvement in the frequency of objective response, the duration of progression-free interval, and the length of survival as compared to standard doxorubicin-cisplatin chemotherapy. 2) To determine if there are any significant differences in toxicity between circadian-timed delivery of doxorubicin-cisplatin chemotherapy versus standard delivery of doxorubicin-cisplatin chemotherapy.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open for patient entry. One patient enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 143 Status: Ongoing

Title: Familial and Reproductive Factors in Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Compute prevalence rates for cancer of the ovary, breast, colon and uterus in first- and second-degree relatives of ovarian cancer cases. 2) Identify that subset of multicase families who would be candidates for linkage analysis studies in the companion GOG Protocol 144. 3) Estimate by fitting major gene models to familial ovarian cancer incidence. 4) Determine if established reproductive risk factors (parity, oral contraceptive (OC) use, tubal ligation) alter risk in women with a positive family history. 5) To collect and store a blood sample from each participant in the study for storage and subsequent gene frequency analysis.

Technical Approach: As outlined in the study protocol.

Progress: Study remains open for patient enrollment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 145 Status: Ongoing

Title: A Randomized Study of Surgery Versus Surgery Plus Vulvar Radiation in the Management of Poor Prognosis Primary Vulvar Cancer and of Radiation Versus Radiation and Chemotherapy for Positive Inguinal Nodes

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purposes of this study are: (1) to evaluate the role of post-operative vulvar irradiation in addition to vulvar surgery for control of the primary and progression-free interval and survival in patients with vulvar cancer with high-risk factors for vulvar relapse; (2) to assess whether the addition of concurrent chemotherapy to ipsilateral inguinal and pelvic nodal irradiation improves inguino-pelvic control and survival in patients with carcinoma of the vulva with positive inguinal nodes; (3) to determine the comparative rates of inguinal and femoral nodal involvement in node-positive patients; (4) to determine the frequency of patient-reported symptoms, and assess several quality of life components including: physical function, social and emotional well-being and sexual function; (5) to determine any association between histological subtype (basaloid/warty/typical) of the primary lesions and various endpoints, including lymph node metastasis and tumor recurrence; and (6) to determine any association between location (medial/lateral/multifocal) of the primary lesion and various endpoints, including lymph node metastasis and tumor recurrence.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 146C Status: Ongoing

Title: Evaluation of Topotecan (SKF 104864-A) in Recurrent, Platinum-Sensitive Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to estimate the antitumor activity of Topotecan in patients with recurrent, platinum-sensitive ovarian cancer who have failed on higher priority treatment protocols. To determine the nature and degree of toxicity of Topotecan in this cohort of patients.

Technical Approach: As outlined in the study protocol.

Progress: Study closed to patient entry. No patients enrolled.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 149 Status: Ongoing

Title: A Randomized Study of Cisplatin Plus Ifosfamide and Mesna Versus Cisplatin Bleomycin, Ifosfamide and Mesna in Stage IV-B, Recurrent or Persistent Squamous Cell Carcinoma of the Cervix

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if bleomycin plus ifosfamide/mesna plus cisplatin (BIP) improves response rate, response duration, progression-free interval and/or survival in advanced squamous cervical cancer compared to treatment with cisplatin plus ifosfamide/mesna. 2) To compare the toxicities of these two regimens in advanced cervical cancer.

Technical Approach: As outlined in the schema of the study protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 150 Status: Ongoing

Title: A Phase III Randomized Study of Accelerated Hyperfractionated Whole Abdominal Radiotherapy (AHWAR) Versus Combination Ifosfamide-Mesna with Cisplatin in Optimally Debulked Stage I, II, III, or IV Carcinosarcoma (CS) of the Uterus

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To compare treatment outcomes (survival and progression-free interval) and failure patterns in patients without stages I-IV carcinosarcoma (CS) of the uterus ( $\leq 1$  cm residual disease) without extra-abdominal distant disease treated with AHWAR versus cisplatin and ifosfamide/mesna. 2) To determine and compare the incidence and type of acute and late adverse events observed with the two treatment regimens.

Technical Approach: The whole abdomen will be treated with AP-PA parallel opposed fields to a total dose of 3000 Cgy. The pelvis will then be treated by a 4-field box technique to a total pelvic dose of 5000 Cgy.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 151 Status: Ongoing

Title: A Phase II Trial of Intraperitoneal Paclitaxel (Taxol) as Salvage Therapy in Patients with Small Volume Residual Ovarian Cancer Following Initial Systemic Chemotherapy

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the surgically defined objective response rate of intraperitoneal paclitaxel when administered on a weekly schedule to patients with small volume residual ovarian cancer, carcinoma of the fallopian tube or primary peritoneal carcinoma following initial systemic chemotherapy and to further evaluate the safety of intraperitoneal paclitaxel administered on a weekly schedule as a salvage treatment program to patients with ovarian cancer.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 152 Status: Ongoing

Title: A Phase III Randomized Study of Cisplatin (NSC #119875) and Taxol (Paclitaxel) (NSC #125973) with Interval Secondary Cytoreduction Versus Cisplatin and Paclitaxel in Patients with Suboptimal Stage III & IV Epithelial Ovarian Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purposes of this study are to determine if the addition of a second surgery during chemotherapy improves survival in patients with advanced ovarian cancer and to determine the effect of this treatment on the quality of the patient's life.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 153 Status: Ongoing

Title: A Phase II Study of Recurrent and Advanced Endometrial Carcinoma Treated with Alternating courses of Megestrol Acetate (Megace) an Tamoxifen Citrate (Novaldex)

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the objective response rate and progression-free interval in patients receiving alternating megestrol acetate (Megace) and tamoxifen citrate (Nolvadex) and to determine the toxicity of alternating megestrol acetate and tamoxifen citrate.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 154 Status: Ongoing

Title: Human Immunodeficiency Virus (HIV) Testing in Patients with Invasive Cervical Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is (1) to obtain preliminary data comparing the clinical course, response to therapy and toxicity of therapeutic regimens for HIV-positive women to those for HIV-negative women with similar disease status; (2) to correlate HIV serostatus with various clinical, pathologic, epidemiologic and demographic factors; and (3) to determine the frequency of positive HIV serostatus among patients age 50 or under who present with invasive cervical cancer and who consent to HIV testing.

Technical Approach: As outlined in the attached protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 155

Status: Ongoing

Title: Evaluation of Alpha-Interferon and Isotretinoin with or without Zidovudine (AZT) in HIV-infected patients with invasive cervical carcinoma and to determine the nature and degree of toxicity and effect on immune status of alpha-interferon and isotretinoin with or without zidovudine in this cohort of patients.

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 1 Dec 95 Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the antitumor activity of alpha-interferon and isotretinoin with or without zidovudine (AZT) in HIV-infected patients with invasive cervical carcinoma and to determine the nature and degree of toxicity and effect on immune status of alpha-interferon and isotretinoin with or without zidovudine in this cohort of patients.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 156

Status: Ongoing

Title: Randomized Trial of Pelvic Radiation Versus Doxorubicin Plus Cisplatin in Stage IB, Stage IC, IIA and IIB Endometrial Carcinoma

Start date:	Estimated completion date:
Principal Investigator: LTC Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the recurrence incidence, progression-free survival and overall survival rates in women with high-risk endometrial carcinomas confined to the uterus who receive postoperative adjuvant therapy with either pelvic irradiation or systemic chemotherapy consisting of doxorubicin and cisplatin.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: GOG 157 Status: Ongoing

Title: A Randomized Phase III Trial of Carboplatin (AUC 7.5) and Paclitaxel 175 mg/m<sup>2</sup> A 21 days x3 Course Versus the Same Regimen x6 Courses, in Patients with Selected Stage IC and II (A,B,C) and Selected IA and IB Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to compare two different courses of two different drugs, paclitaxel (Taxol) and carboplatin.

Technical Approach: Once the patient has been determined eligible, treatment will be as outlined in the schema of the protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: GOG 158

Status: Ongoing

Title: A Phase III Randomized Study of a Platinum Compound and Paclitaxel in Optimal Stage III Epithelial Ovarian Carcinoma: Cisplatin and Paclitaxel (24-Hour Infusion) Versus Cisplatin and Paclitaxel (96-Hour Infusion) Versus Carboplatin and Paclitaxel (3-Hour Infusion)

Start date:

Estimated completion date:

Principal Investigator:

MAJ Kevin Hall, MC

Facility:

Brooke Army Medical Center, Texas

Department/Service:

Department of Obstetrics and Gynecology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate whether any of two experimental programs for the treatment of ovarian cancer is better than the standard therapy currently used.

Technical Approach: Once the patient has been determined eligible, treatment will be as outlined in the schema of the protocol.

Progress: This is a new study. There is no reportable data.